



Ref. No.: F.02(368)/RMSCL/PROCUREMENT/DRUG/NIB-01/2023/50 Dated:- 06.01.2023

RAJASTHAN MEDICAL SERVICES CORPORATION LTD.

(A Govt. of Rajasthan Undertaking)

Gandhi Block, Swasthya Bhawan, Tilak Marg, Jaipur – 302005, India

Tel No: 0141-2228066, 2228064, E-mail: rmsc@nic.in, edprmsc@nic.in

**E-BID FOR RATE CONTRACT AND EMPANELMENT OF
MANUFACTURER FOR SUPPLY OF DRUGS AND
MEDICINES**

(Rate Contract for the period ending on 31.12.2023)



!! सर्वे सन्तु निरामया:!!

LAST DATE OF SUBMISSION OF ONLINE BIDS	30.01.2023 & 06.00 PM
DATE AND TIME OF OPENING OF ONLINE TECHNICAL BIDS	31.01.2023 & 11.00 AM

**RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
(A Govt. of Rajasthan Undertaking)**

Gandhi Block, Swasthya Bhawan, Tilak Marg, Jaipur – 302005, India

Phone No: 0141-2228066, 2228064

Website: www.rmsh.health.rajasthan.gov.in

CIN:U24232RJ2011SGC035067

E-mail : edprmsc@nic.in

Ref. No.: F.02(368)/RMSCL/PROCUREMENT/DRUG/NIB-01/2023/50 Dated:- 06.01.2023

Notice Inviting E-Bid

e-bids are invited for RATE CONTRACT AND EMPANELMENT OF MANUFACTURER FOR SUPPLY OF DRUGS AND MEDICINES upto 06.00 PM on 30.01.2023 (Estimated Cost Rs 18 Cr.)

Details of NIB may be seen at the website of State Public procurement Portal <http://sppp.rajasthan.nic.in>, <http://eproc.rajasthan.gov.in>, <http://rmsh.health.rajasthan.gov.in> and may be downloaded from there.

UBN.No.....

**Executive Director (Procurement)
RMSCL**

-

**RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
RAJASTHAN**

**E-BID FOR RATE CONTRACT CUM SUPPLY AND EMPANELMENT FOR SUPPLY OF
DRUGS AND MEDICINES**
(Rate Contract for the period ending on 31.12.2023)

Bid Reference	: F.02(368)/RMSCL/PROCUREMENT/DRUG/NIB- 01/2023/50 Dated:- 06.01.2023
Date and time for downloading bid document	: 07.01.2023 from 9.00 AM
Pre Bid	: 10.01.2023 AT 11.00 AM
Last date and time of submission of online bids and e-deposit	: 30.01.2023 at 6.00 PM
Date and time of opening of Online technical bids	: 31.01.2023 at 11.00 AM
Tender Cost	: 18 Cr.
Cost of the Bid Document	: Rs. 2360/- (Including GST@ 18%)
Cost of the Bid Document For MSME Unit of Rajasthan	: Rs. 1180/- (Including GST @ 18%)
RISL Processing Fees	: Rs. 1180/- (Including GST @ 18%)
Empanelment Fees	: Rs. 5900/-(Including GST @ 18%)

INDEX

S.NO	PARTICULARS
	General instruction for bidders
1.	Last date for receipt of bids, bid document fees, Bid Security Deposit, RISL processing fees and empanelment fees
2.	Eligibility criteria
3.	Purchase preference
4.	General conditions
5.	Technical bid
6.	Price bid
7.	Opening of technical and financial evaluation
8.	Bid security deposit
9.	Other conditions
10.	Acceptance of bid
11.	Security deposit (performance guarantee)
12.	Agreement
13.	Supply conditions
14.	Logograms / markings
15.	Packing
16.	Quality testing
17.	Payment provisions
18.	Deduction in payments:
19.	Quality control deduction & other penalties:
20.	Empanelment of bidders (mandatory)
21.	Saving clause
22.	Jurisdiction
23.	Correction of arithmetic errors
24.	Procuring entity's right to vary quantity
25.	Dividing quantities among more than one bidder at (in case of procurement of goods):
26.	Grievance redressal during procurement process:
27.	Compliance with the code of integrity and no conflict of interest:
28.	Fall Clause
29.	Annexure-I Bank Challan
30.	Annexure -II Format of Affidavit
31.	Annexure -III Annual Turn Over Statement
32.	Annexure -IV Agreement
33.	Annexure - V Check List
34.	Annexure - VI Check List of Details Regarding Products Quoted
35.	Annexure - VII Declaration & Undertaking
36.	Annexure - VIII List of Drugs With Specifications
37.	Annexure - IX Guidelines for Blacklisting/Debaring of Product or Supplier/Company
38.	Annexure - X Memorandum of Appeal Under The Rajasthan Transparency In Public Procurement Act, 2012
39.	Annexure -XI Undertaking For Empanelment
40.	Annexure -XII Supplier Consolidated Invoice
41.	Annexure -XIII Analytical Report Regarding Quality
42.	Annexure -XIV Security form (Bank guarantee)

GENERAL INSTRUCTIONS FOR BIDDERS

The bidders are instructed to read the complete bid document carefully. The following points may be noted so that mistakes/lapses/shortcomings during Bid submission can be avoided.

1. It is expected from all bidders that they will ensure that documents to be used in bid set will be given to a reliable person only, and that only a fully reliable person shall be authorized for DSC. So that the confidentiality of your bid/ rates can be maintained upto bid opening & that your documents are not put to any misuse.
2. It is advisable for bidder to authorize only those persons for RMSCL tender who are employed in your company on salary basis.
3. The turnover should be as per bid conditions. Do not submit Bid if the turnover of the firm is less.
4. Quote only for the products for which Product Permission meets the Bid specifications. Do not quote if it differs with regard to any parameter.
5. **Quote rate in BOQ for the packing unit exactly given in annexure VIII.**

For example :-

- If the packing unit is given for 10x10 tablets / capsule, the rate should be quoted for 10x10 tablets / capsule, and not for 1 tablet / capsule or 10 tablets/ capsule.
- If the packing unit is given for 10x10x1 tablets / capsule, the rate should be quoted for 10x10x1 tablets / capsule, and not for 1 tablet / capsule or 10 tablets/ capsule.
- If the packing unit is given for 10x14 tablets / capsule, the rate should be quoted for 10x14 tablets / capsule, and not for 1 tablet / capsule or 10 tablets/ capsule.
- If the packing unit is given for 2 ml ampoule (25 ampoules), the rate should be for 25 ampoules and not for 1 ampoule or 10 ampoules etc.
- If the packing unit is given for 2 ml ampoule (10 ampoules), the rate should be for 10 ampoules and not for 1 ampoule etc.

6. Highlight the quoted items in the documents like Product Permission and Market Standing Certificate, and also mark the item code no. at appropriate place in the documents.
7. The uploaded product permission and other documents should be clearly legible. Date of issue of the documents should be clearly legible.
8. Upload the Bids on the e-portal well in advance so that failure in uploading can be avoided and no desired document remains un-uploaded.
9. In case there is any suggestion regarding Bid conditions/specifications/shelf life, strength, packing/turn over etc. The suggestions should be submitted/sent/E – Mailed one/two days earlier from the date of pre bid meeting so that the representation of the bidders may be well processed and decision could be taken well in time. **After pre bid meeting date no representation/ suggestions will be entertained.**
10. If there is any query regarding terms and conditions in Bid document, you may contact :-

Sh. Rajesh Kumar Gupta, Senior Manager (Proc)

Ph.0141-2228064, Mob. No. 93140-78838

Sh. Deepak Sharma, Senior Manager (Drug)

Ph.0141-2228064, Mob. No. 88752-98700

**RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
RAJASTHAN**

Rajasthan Medical Services Corporation Ltd., (hereinafter referred to as Bids Inviting Authority unless the context otherwise requires) invites **E-BID FOR RATE CONTRACT CUM SUPPLY AND EMPANELMENT FOR SUPPLY OF DRUGS AND MEDICINES.**

1. LAST DATE FOR RECEIPT OF BIDS, BID DOCUMENT FEES, BID SECURITY DEPOSIT, RISL PROCESSING FEES AND EMPANELMENT FEES

- (a) E-Bid in two separate bids (Technical bid & Price Bid)] will be received till 30.01.2023 at **6.00 PM** by the Rajasthan Medical Services Corporation Ltd, for the E-BID FOR RATE CONTRACT CUM SUPPLY AND EMPANELMENT FOR SUPPLY OF DRUGS AND MEDICINES. (**Rate Contract for the period ending on 31.12.2023**)
- (b) The bid should be valid for a Period of 120 days from the date of opening of Technical Bid and prior to the expiration of the bid validity the Bid Inviting Authority may request the Bidders to extend the bid validity period for an additional specified period of time. The Bidder may refuse extension of bid validity, and in such a case its Bid security deposit shall not be forfeited.
- (c) Bid form fee Rs. 2360.00 (Including GST @ 18%) (Rs. 1180.00 (Including GST @ 18%) for MSME Units of Rajasthan) for downloading from the website.
- (d) Bid Security Deposit as applicable in Bid condition no. 8.
- (e) Processing fee of Rs.1180.00 (Including GST @ 18%) of R.I.S.L.
- (f) **Bidders which are found eligible / responsive on technical grounds / criteria would be empanelled for those item for which they have bided in the NIB as per Annexure VIII. Empanelment is mandatory for all eligible firms / bidders. A fee of Rs 5900 (including GST @18%) in the form of DD (in favour of MD, RMSCL)/challan/e-deposit is to be submitted along with bid for empanelment.. Please see clause 20 and Annexure-XI in this regard.**
It is clarified that all bidders are require to submit Empanelment fees which

is valid for one financial year. Those bidders who have already submitted Empanelment fees in previous bid (Drugs & Medicines NIB-13/2022, NIB-14/2022 , NIB-15/2022, 16/2022 and 17/2022), they need not submit Empanelment fees .

These fees are to be paid through three separate prescribed challans (*format enclosed in Annexure- I*) in any branch of the Punjab National Bank Account no. 2246002100024414 & IFSC Code no. PUNB0224600 throughout country upto 30.01.2023 or through D.D. / bankers cheque in favour of M.D. RMSCL (Bid document fees, Bid security and **Empanelment fees**)/ M.D. RISL (Bid processing fees) physically in the office of RMSCL on 30.01.2023 upto **6.00 PM**. The bidders shall submit/upload scanned copy of all the challans/DD/ e – deposit generated receipt in Technical Bid. Bids will be opened only after ensuring receipt of Bid document fees along with processing fees, Bid Security Deposit and Empanelment fees. In the absence of Bid document fees and processing fees , Bid Security Deposit and Empanelment fees the Bids will be rejected and will not be opened.

Note:- (I) While the Bid uploading it would be asked on e procurement website about Bid Security, whether it is Rs. 2.00 lacs or Rs. 5.00 lacs , the bidder may mention any option for the purpose of Bid uploading but has to submit required Bid Security as specified in clause no 8.

Note:- (II) There is no option of online payment of tender fee, processing fee, bid security etc. on e-procurement portal.

Click on offline mode (either DD or BC) on e procurement portal for the purpose of bid uploading only.

2. ELIGIBILITY CRITERIA

- (a) Bidder should be a manufacturer having valid manufacturing licence/loan licence or direct importer holding valid import licence. Distributors/ Suppliers / Agents are not eligible to participate in the Bids.
- (b) Average Annual turnover (for drugs and medicines including Surgical and sutures Business) in the last three financial years 2018-19, 2019-20 & 2020-21 or 2019-20, 2020-21 & 2021-22 should not be less than Rs. 20 Crores.

-
For MSME units of Rajasthan, the average annual turnover in the last three financial years 2018-19, 2019-20 & 2020-21 or 2019-20, 2020-21 & 2021-22 should not be less than Rs. 10 Crore.

For drug items falling in the category of Disinfectants & Antiseptics, Eye preparations and Ear drops etc bidder's firms average annual turnover of last three financial years should not be less than Rs. 2 Crore(item code 332).

Only audited accounts would be considered provisional accounts would not be considered in any case.

Explanatory Note:-

- 1) The merger / amalgamation / transfer of business / transfer of assets etc. of a firm affect the bid condition relating to 'Turnover' in preceding years. The eligibility of a bidder in this regard shall be ascertained on the basis of a certificate issued by a competent authority regarding amalgamation / transfer of business / transfer of assets.
- (c) Bidder should have at least 3 years market standing as a manufacturer for the items quoted in the bid, on the date of bid opening. In the case of imported products, the product should have minimum 3 years standing in the market. The importer should have at least 3 year standing as manufacturer/ importer of drugs in general. Imported drugs shall be accepted in brand name also. **The period of Market Standing will be reckoned from the date of issue of Product Permission.**

Explanatory note:-

“In case of imported products, market standing for the product in international market would be considered for establishing eligibility regarding this particular clause of the bidding document. Also if a bidder is manufacturing a product abroad at various locations/countries and participating in the bid quoting a product being manufactured at a particular place, market standing of the product manufactured at other than particular place would be considered.”

- (d) Bidder should have permission to manufacture the item /drug quoted as per specification given in the Bid from the competent authority. Product permission of *brands* shall be accepted in the Bid submitted, but the Bidder has to submit the product permission in generic names at the time of signing of the agreement/before supply.
- (e) **Bid should not be submitted for the product/products for which the concern/company stands blacklisted /banned/debarred on the date of bid submission either by Bid inviting Authority or Govt. of Rajasthan or its departments on any ground. The Bid should not be submitted for those products also for which the concern/company stands blacklisted/banned/debarred on the date of bid submission by any other State/Central Govt. or it's any agencies (central Drugs procurement agencies) on the ground of conviction by court of law or the products being found Not of Standard Quality. (NoSQ)**
- (f) **The concern/company/firm which stands blacklisted/banned/debarred on any ground either by Bid Inviting Authority (RMSCL) or Govt. of Rajasthan or its departments on the date of bid submission, shall not be eligible to participate in the Bid. The concern/company/firm which stands blacklisted/banned/debarred on the ground of conviction by court of law or the products being found Not of Standard Quality (NoSQ) by any other State /Central Government or it's any agencies (central Drugs procurement agencies) shall also not be eligible to participate in the Bid. For Specific cases regarding other quality issues the purchase committee of RMSCL may decide the case on merit basis.**
- (g) If any product/products of a company/firm have been declared as not of standard quality, as per Drugs & Cosmetics Act during last 2 years anywhere, such concern/company/firm shall not be eligible to participate in Bid for such product/products. If any company/firm is found to have any such product quoted in the Bid, the product shall be blacklisted for 2 years and a penalty equivalent to Bid Security Deposit shall also be levied. [Penalty should be minimum and maximum as per bid security given in clause 8] In such situation, the bid will be considered further only if the amount of penalty is deposited before the completion of technical evaluation.
- (h) The concern/firm/company whose product has been declared as of spurious or adulterated quality and any criminal case is filed and pending in any court shall

not be eligible to participate for that particular product, in the Bid. Similarly convicted firm/company shall also not be eligible to participate in the Bid.

- (i) If a company has two or more separate manufacturing units at different sites/states, the company will be allowed to submit only one Bid for all units but necessary document regarding separate manufacturing units will be submitted as a separate set with the same Bid. But a bidder will be allowed to submit only one offer for one product.

3. PRICE PREFERENCE AND PURCHASE PREFERENCE

- (1) Price preference is not applicable as GST has been made effective from 01.07.2017 in place of VAT.
- (2) Purchase preference shall be given to MSME's unit of Rajasthan as per notification of Finance (GF&AR Division) Department, Government of Rajasthan notification S.O.165 dated 19.11.2015).

4. GENERAL CONDITIONS

- i. At any time prior to the date of submission of Bid, Bid Inviting Authority may, for any reason, whether on his own initiatives or in response to a clarification requested by a prospective Bidder, modify the condition in Bid documents by way of amendment. In order to provide reasonable time to take the amendment into account in preparing their bid, Bid Inviting Authority can at his discretion, extend the date and time for submission of Bids.
- ii. Interested eligible Bidders may obtain further information in this regard from the office of the Bid Inviting Authority, i.e RMSCL.
- iii. In case any document submitted by the bidder or his authorized representative is found to be forged, false or fabricated, the bid will be rejected and Bid Security/Performance Security will be forfeited. Bidders or their representative may also be blacklisted/banned/debarred. Report with police station can also be filed.

5. TECHNICAL BID

The Bidder should furnish the following in technical bid:-

- (a) Bidders are allowed the option to quote for anyone item or more items as mentioned in bid (list of medicines proposed to be purchased at Annexure-VIII). The amount of Bid Security Deposit will be Rs. 20,000/- per item of drug quoted subject to minimum of Rs.2.00 lacs and maximum of Rs. 5.00 lacs.
- (b) The bidders shall submit/upload scanned copy of all the challans, D.D./ BC/ e-deposit generated receipt annexed with Technical Bid in proof of deposition / submission of Bid document fees, RISL processing fee and Bid security. The required Bid Security Deposit / Bid document fees/ RISL fee / Empanelment fees may be in form of physical D.D./ BC and should be in favour of M.D. RMSCL (bid document fees and Bid Security Deposit), MD, RISL (bid processing fees).
- (c) Empanelment as supplier for Drugs and Medicines are required to deposit separately an Empanelment Fee of Rs 5900 (including GST @ 18%) in the form of DD /challan/e-deposit in favour of MD, RMSCL before due time and date of bid submission.
- (d) Documentary evidence for the constitution of the company/Firm such as Memorandum and Articles of Association, Partnership Deed etc. with details of the Name, Address, Telephone Number, Fax Number, e-mail address of the firm and of the Managing Director/Partners/Proprietor.
- (e) The Bidder should furnish attested copy of the valid Licence for the product duly approved by the Licensing authority for each and every product quoted as per specification in the Bid. The licence must have been duly renewed/ valid up to date and the items quoted shall be clearly highlighted (Bid item codes marked against each item) in the licence.
- (f) Attested photocopy of the valid import licence in Form 10 with Form 41 (as per Rule 122A of Drugs and Cosmetics Act), if the product is imported. The licence must have been renewed /valid up to date. A copy of a valid licence for the sale of Drugs imported by the firms issued by the licensing authority shall be enclosed.

- (g) The instruments such as power of attorney, resolution of board etc., authorizing an officer of the Bidder should be enclosed.
- (h) Authorization/nominating a responsible person of the Bidder to transact the business with the Bid Inviting Authority with photograph and signature in Annexure VII.

- (i) Bidder should have at least 3 years market standing as a manufacturer for the items quoted in the bid.

For imported items, the quoted item should have 3 years market standing, for which bills of entry, sale invoices, etc should be submitted in token of proof. The importing firm should have 3 years standing as importer / manufacturer of medicines in general. The importer firm may submit Bills of entry, etc of same or other Surgical /Drugs to establish the market standing of the firm. The bidder shall submit valid import licence for direct import of the quoted item.

- (j) Market Standing Certificate issued by the Licensing Authority / competent authorities as a Manufacturer for the product for last 3 years (Certificate should be enclosed with list of items) should be enclosed. Items quoted should be highlighted in the market standing certificate. The Market Standing Certificate should not have been issued by competent authority more than 2 years old as on the last date of bid submission. The bidder shall submit valid import licence for import of the quoted item.
- (k) Non-conviction Certificate issued by the Drugs Controller of the State. It should be recent and not more than one year old.
- (l) WHO-GMP (WHO - Good manufacturing practices Certificate) Certificate issued by the Licensing Authority. The WHO-GMP certificate must not be older than one year from the due date of Bid submission in the case where validity is not mentioned in the certificate. The WHO-GMP certificate of all the manufacturing plants, of which products have been quoted, should be submitted. The Bidder shall also furnish an undertaking in the format given

in Annexure-VII point no.8 declaring that the Bidder complies with the requirements of WHO-GMP.

WHO-GMP certificate is relaxed to WHO-GMP/GMP certificate for item code 217, 564 and 687.

The Importer should produce WHO- GMP / COPP of the manufacturing firm or a certificate which is at par with WHO-GMP issued by exporting countries like US- FDA approval, etc. In the case of imported drugs, labels and product literature of all quoted products must be submitted.

The Firm will continue to hold WHO-GMP Certificate for the product during entire rate contract period of the product. If WHO-GMP certificate expires, it is firm's responsibility to inform RMSCL about the same and not to accept any further purchase order till re-issue /renewal of WHO-GMP certificate. During the period of non validity of WHO-GMP certificate of the firm the rate contract will deemed to be suspended. If the firm fails to inform RMSCL about the expiry of WHO-GMP certificate and accept purchase order of RMSCL and later on it comes to the knowledge of RMSCL, in this situation firm shall be liable for a panel action.

- (m) Annual turnover statement for 3 years i.e., 2018-19, 2019-20 & 2020-21 or 2019-20, 2020-21 & 2021-22 in the format given in Annexure-III should be certified by the practicing Chartered Accountant.
- (n) Copies of the Balance Sheet and Profit and Loss Account for three years i.e. 2018-19, 2019-20 & 2020-21 or 2019-20, 2020-21 & 2021-22 duly certified by the practicing Chartered Accountant will have to be submitted with bid.
No provisional Balance sheet and / or provisional Profit and Loss account would be considered.
- (o) GST return 30.09.2022 or latest Months.
- (p) Details of GST registration. The industries situated in GST free zones will produce the copy of appropriate notification. Bidders have to submit GSTIN number and state where GSTIN registered for every quoted items for which supply will be made. (Annexure VII at point no 3)

- (q) Undertaking (as in Annexure-VII) for embossment of logo on labels as per conditions specified at Clause 14 herein.
- (r) Undertaking that the manufacturer has not been blacklisted, the product never been declared as not of standard quality during last two years, it's manufacturing capacity and other details required on a format mentioned at Annexure-VII.
- (s) Details of technical personnel employed in the manufacture and testing of drugs (Employee Name, Qualification, and Experience) as enclosed in license.
- (t) List of items quoted to be shown in the Annexure-VII point number 6
- (u) A Checklist (Annexure-V) for the list of documents enclosed with their page number. The documents should be serially arranged as per Annexure-V. Every bidder will also be required to submit details of product permission of the quoted item and the desired market standing, in Annexure- VI
- (v) An undertaking that the bidder complies with all the terms, conditions, amendments (if any) of bid document to be submitted in Annexure-VII point no.11.
- (w) A declaration under Section 7 of Rajasthan Transparency in Public Procurement Act, 2012 in Annexure-VII point no. 13
- (x) All copies submitted should be self attested.
- (y) An undertaking in Annexure-XI that the bidder wishes to get empanelled as supplier for the quoted items and has submitted the necessary fee for the same. (This is only for those who apply for empanelment also).
- (z) A copy of PAN issued by Income Tax Department.

Note:- 1. Clarification regarding submission of documents

- 1. Bidders are again advised to fill the Annexure-VII very carefully as after bid opening any amendment in Annexure-VII would not be allowed in any case. Bidders should ensure that self certified copies of all relevant documents i.e. Product Permission, WHO-GMP certificate, Market standing certificate etc. should be in accordance with the license no. / Product Permission mentioned in the Annexure VII. Bids Submitted without dully filled Annexure-VII would be declared Non-Responsive.**

2. ***Bidders who fail to submit copies of documents as under, would summarily declared as non-responsive:-***

- (a) ***In case copies of Product Permission either not submitted or not as per tender conditions/specifications of the item; If Product Permission is as per specifications of item mentioned in the tender but it's for export purpose, the Product Permission for domestic manufacturing would be accepted only when asked through clarification and provided that such Product Permission for domestic manufacturing has been issued on or before the last date of bid submission.***
- (b) ***If copies of WHO-GMP certificate and/or Non-Conviction certificate and/or Market Standing Certificate have not been submitted in main bid or not as per tender condition/item specifications. It has also been observed that in certain cases, licensing authority takes time in issuance / renewal of aforesaid certificates, in such cases bidders have to invariably enclose expired documents/certificates along with copy of acknowledgment of application for renewal of such documents filed with licensing authority. In such cases bidders would be allowed to submit renewed documents at the time of clarification sought by the RMSCL, provided that the renewed documents should have been issued on or before the date of submission of clarifications as sought by the RMSCL.***

6. **PRICE BID –**

The price bid will also be known as financial document and every bidder will be required to submit its price in excel format attached to the bid document (BOQ). BOQ template must not be modified/ replaced by the bidder and the same should be uploaded after filling the relevant columns, else the bidder is liable to be rejected for this bid. Bidders are allowed to enter the bidder name and values only. **The bidder should quote rate for the mentioned packing unit only.**

7. **OPENING OF TECHNICAL AND FINANCIAL EVALUATION**

The Bid will be scrutinized by Bid evaluation committee and inspection of manufacturing unit for compliance of WHO-GMP may be carried out by technical committee. Price Bid (BOQ) of the Bidder found eligible on satisfying the criteria for technical evaluation and inspection, will only be opened.

8. **BID SECURITY**

The Bid Security shall be @ Rs. 20,000/- for each item of Drugs & Medicines quoted subject to minimum of Rs. 2.00 lacs and maximum of Rs. 5.00 Lacs. In case Bid Security submitted by the bidder is at the minimum or more but number of quoted items is more than the Bid Security submitted, the quoted items by the bidder will be counted in sequence up to the Bid Security deposited. However without minimum Bid Security the offer will not be considered at all., Bid

Security will not be taken from undertakings, corporation of GoI & GoR. Further, Bid Security will be taken @ Rs. 5,000/- per item of Drugs & Medicines quoted subject to minimum of Rs. 50,000/- and maximum of Rs. 1.25 Lacs, from MSME Units of Rajasthan. They will furnish copy duly attested by gazetted officer of the registration of MSME units of Rajasthan issued by the Director of Industries in respect of the stores for which they are registered. Duly attested copy of Acknowledgement of EM-II issued by DIC with an affidavit worth Rs.100 as per Annexure-II under preference to Industries of Rajasthan rules 1995 in respect of stores for which they are registered. (Annexure-II(B)). In case Bid Security submitted by the bidder is at the minimum or more but number of quoted items is more than the Bid Security submitted, the quoted items by the bidder will be counted in sequence up to the number matching the Bid Security deposited. However without minimum Bid Security the offer will not be considered at all.

The Bid Security shall be paid through separate prescribed challans (format enclosed in Annexure-I) in any branch of the Punjab National Bank Account no. 2246002100024414 (IFSC Code no. PUNB0224600) throughout country upto 30.01.2023 or through D.D. / bankers cheque in favour of M.D. RMSCL physically in the office of RMSCL on or before 30.01.2023 upto 6.00 PM. Bid security Deposit in any other form will not be accepted.

The Bids submitted without sufficient Bid Security will be summarily rejected. The Bid Security will be forfeited, if the Bidder withdraws its Bid after last time & date fixed for receiving bids or in the case of a successful Bidder, if the Bidder fails within specified time to sign the contract agreement or fails to furnish the performance security.

9. OTHER CONDITIONS

1. The orders will be placed by the Managing Director or any officer designated, Rajasthan Medical Services Corporation Ltd, (hereinafter referred to as Ordering Authority).
2. **The details of the required drugs, medicines, etc., are shown in Annexure-VIII. The quantity mentioned is only the tentative requirement and may**

increase or decrease as per the decision of Ordering Authority. The rates quoted should not vary with the quantum of the order or the destination. The commitment quantity for an item submitted by the bidder (in Annexure VII) shall be taken into account. The whole commitment quantity to be supplied during contract period should not be less than estimated bid quantity. As well, the monthly commitment quantity should not be less than 10 % of the whole commitment qty. A bidder having manufacturing capacity less than commitment quantity (either monthly or for whole contract period) may be technically disqualified.

3. e- Bid has been called for in the generic names of drugs. The Bidders should quote the rates for the generic products. The composition and strength of each product should be as per details given in Annexure-VIII. Any variation, if found, will result in rejection of the Bid. The products should conform to the specified standards IP/BP/USP. In case the product is not included in the said compendium, the supplier, upon award of the contract, must provide the reference standards and testing protocols for quality control testing.
4. Rates (inclusive of **all expenses / charges but exclusive of GST**) should be quoted for each of the required drugs, medicines etc., separately on door delivery basis according to the unit ordered. Bid for the supply of drugs, medicines, etc. with conditions like “AT CURRENT MARKET RATES” shall not be accepted. Handling, clearing, transport charges etc., will not be paid. The delivery should be made as stipulated in the purchase order placed with successful Bidders. No quantity or cash discount should be offered.
5.
 - a) To ensure sustained supply without any interruption, the Bid Inviting Authority reserves the right to fix more than one supplier to supply the requirement among the qualified Bidders
 - b) Orders will be placed periodically during rate contract period based on the RMSCL's requirement to the firms approved for rate contract as per above clause no. 3 . After the conclusion of Price Bid opening, the lowest offer of the Bidder, if required will be considered for negotiations, and rate arrived after negotiations will be L-1 rate and L-1 supplier for an item of drugs/medicines for which the Bid has been invited.

- c) The Bidder who has been declared as L-1 supplier for certain item or items of drugs/medicines shall execute necessary agreement for the supply of the Bided quantity of such drugs/medicines as specified in the Bid document on depositing the required amount as performance security and on execution of the agreement, such Bidder is eligible for the placement of purchase orders. Moreover, purchase order can be placed after the issue of letter of acceptance, pending the execution of agreement and issuance of rate contract for an item.
- d) RMSCL will inform the L1 rate to the Bidders who qualified for Price Bid opening, through RMSCL web site or e-mail; willing bidders may inform in writing their consent to match with the L-1 rate for the item of the Drugs/Medicines quoted by them and the Bidders who agree to match L1 rate, will be considered as Matched L1.
- e) The Bidder, who agrees to match L-1 rate shall furnish the breakup detail (Rate, GST etc.) of price (L-1 rate).
- f) The supplier upon receipt of the purchase order finds that the purchase orders exceeds the production capacity declared in the Bid documents and the delay would occur in executing the order, shall inform to the RMSCL immediately without loss of time and the purchase order shall be returned within 7 days from the date of the order, failing which the supplier is stopped from disputing the imposition of liquidated damages, fine for the delayed supply.
- g) If the L1 supplier has failed to supply /intimated RMSCL about his inability/delay in supply as per the purchase order, the required Drugs/Medicines within the stipulated time or as the case may be, RMSCL may also place purchase orders with the L1 Rate Matched Bidder for purchase of the Drugs/Medicines, provided such rate matched Bidders shall execute necessary agreement indicating the production capacity as specified in the Bid document on depositing the required amount. Such Bidder is eligible for the placement of purchase orders for the item or items of Drugs/Medicines quoted by them.

- h) Subject to Para (g) above, while RMSCL has chosen to place purchase orders with Matched L1 supplier and there are more than one such matched L1 suppliers, then the purchase orders for the requirement of Drugs/Medicines will be placed with L-2 first on matched rates of L-1 and in case L-2 does not have the required capacity than L-3 would be considered on matched L-1 rates and the same order would be followed in case of L-3, L-4 etc.
- i) The matched L1 supplier, on placement of purchase orders, will be deemed as L-1 rate supplier for the purpose of the Bid and all provisions of the Bid document applicable to L-1 rate Bidder will apply mutatis mutandis to the matched L1 supplier.
- j) If the purchase order quantity is very less (which do not make even a normal small batch size; order quantity is less than 1 lac Tab/Cap, or less than 10,000 injections/ bottles/ tubes), the supply may be allowed in brand name to ensure uninterrupted sustained supply. However, the label should possess the required logogram, and the price should not appear on the label.
6. The rates quoted and accepted will be binding on the Bidder during validity period of the bid and any increase in the price (except increase in **GST rate** or any other statutory taxes) will not be entertained.
7. No Bidder shall be allowed to claim revision or modification of bid after opening of bid. If any bidder withdraws or modifies its bid after opening of bid the bid security taken from the bidder shall be forfeited. Representation to make correction in the Bid documents on the ground of Clerical error, typographical error, etc., committed by the Bidders in the Bids shall not be entertained after submission of the Bids. Conditions such as “SUBJECT TO AVAILABILITY” “SUPPLIES WILL BE MADE AS AND WHEN SUPPLIES ARE RECEIVED” etc., will not be entertained under any circumstances and the Bids of those who have given such conditions shall be treated as incomplete and accordingly the Bid will be rejected.
8. The rates should be quoted only for the composition stated in the Bid.
9. Supplies should be made directly by the bidder and not through any other agency.

10. The Bidder shall allow inspection of the factory at any time by a team of Experts/Officials of the Bid Inviting Authority and or of the Govt. of Rajasthan. The Bidder shall extend all facilities to the team to enable to inspect the manufacturing process, quality control measures adopted etc., in the manufacture of the items quoted. If a Company/Firm does not allow for any such inspection, its Bid / contract may be rejected.

10. ACCEPTANCE OF BID

1. The Bid evaluation committee formed by Managing Director, Rajasthan Medical Services Corporation Ltd. will evaluate the Bid with reference to various criteria.
2. Bid Inviting Authority reserves the right to accept or reject the Bid for the supply of all or any one or more items of the drugs Bided for in a Bid without assigning any reason.
3. Bid Inviting Authority, or his authorized representative (s) has the right to inspect the factories of Bidders, before, accepting the rate quoted by them, or before releasing any purchase order(s), or at any point of time during the continuance of Bid and also has the right to reject the Bid or terminate/cancel the purchase orders issued and or not to reorder, based on adverse reports brought out during such inspections.
4. The acceptance of the Bids will be communicated to the successful Bidders in writing by the Bid inviting authority. Immediately after receipt of acceptance letter, the successful Bidder will be required to deposit PERFORMANCE SECURITY and agreement but not later than 15 days.
5. **The approved rates of the successful Bidders would be valid upto 31.12.2023 (w.e.f date of letter of acceptance) and extendable upto 3 months, if required. Firm shall be bound to accept the extension period of Rate Contract.**
6. Moreover, purchase order can be placed after the issue of letter of acceptance, pending the execution of agreement and issuance of rate contract for an item.

11. PERFORMANCE SECURITY

The Successful Bidders shall be required to pay performance Security Deposit @ 2.5% of the Contract value. Performance security will not be taken from undertaking, corporation of GoI & GoR. The MSME Units of Rajasthan shall be required to pay Performance security @ 0.5% of the contract value.

The performance security shall have an upper limit of Rs 25 Lac to be deposited by a bidder at the time of signing of agreement (For one or many items). However, when the actual purchase orders cross a threshold for requiring additional security, the same will be required to be deposited by the supplier.

The performance guarantee should be paid upfront in respect of each contract on or before the due date fixed by Bid inviting authority in the form of Bank Guarantee (Performa given in Annexure XIV) in case the amount exceeds Rs. 5 Lakhs. For amount of upto 5 Lakhs it should be deposited in the form of demand draft/bankers cheque issued by a scheduled bank or may be deposited through challan annexure-1 (the validity of bank guarantee should be for a period of thirty six month from the date of issuance of Bank Guarantee) in favour of the Managing Director, Rajasthan Medical Services Corporation Ltd, Payable at Jaipur before releasing the purchase order by the ordering authority. In case Rate Matched Bidders who have agreed to supply at L-1 price, then the performance security Deposit of such bidders will be 5% of value of quantity fixed for them. (upper limit Rs 25 Lac). Performance Security shall remain valid and refunded 60 days beyond the date of completion of all contractual obligations or after 24 months from the date of issuance of letter of acceptance, whichever is later.

12. AGREEMENT

- a) The successful Bidder shall execute an agreement on a non-judicial stamp paper of value mentioned in the Acceptance Letter (stamp duty to be paid by the Bidder) within 15 days period from the date of Letter of acceptance / Letter of intent or within extended period by the Bid Inviting Authority, i.e. the Managing Director, Rajasthan Medical Services Corporation Ltd. The Specimen form of agreement is available in Annexure-IV. Failing to submission of performance security and execution of agreement within stipulated period as above, will result in forfeiture of Bid Security Deposit & other consequential action. **A bidder who is found successful in more than one product; he will be intimated through**

LOA / LOI to execute agreement for all the products / drugs / items. If such bidder will not execute agreement for one or more items, in such situation a penalty equal to minimum bid security e.i. Rs. 2.00 Lacs and in case of MSME Rs. 50000/- shall be imposed and the product for which agreement is not executed shall be debarred for a period of not less than 3 years.

- b) The Bidder shall not, at any time, assign, sub-let or make over the contract or the benefit therefore or any part thereof to any person or persons whatsoever.
- c) All notices or communication relating to, or arising out of this agreement or any of the terms thereof shall be considered duly served on or given to the Bidder if delivered to him or left at the premises, places of business or abode.

13. SUPPLY CONDITIONS

- 1. Purchase orders along with the delivery destinations will be placed on the successful Bidder at the discretion of the Ordering Authority. Drugs and Medicines will be supplied at 34 district drug ware houses and 6 Medical College Warehouses of Rajasthan.
- 2. The supplier shall supply the entire ordered quantity before the end of **60 days** from the date of issue of purchase order at the destinations mentioned in the purchase order, if the above day happened to be a holiday for RMSCL, the supply should be completed by 5.00 p.m. on the next working day. For drug items requiring sterility test and imported ones, the supply period will be **75 days** from the date of issue of purchase order.
- 3. All supplies will be scheduled for the period from the date of purchase order till the completion of the bid in installments, as may be stipulated in the purchase order.
- 4. **Shelf Life:** The labeled shelf life of drugs supplied should be not less than the period mentioned against each item in list of Drugs (Annexure-VIII). The remaining shelf life of the drugs at the time of delivery should not be less than $\frac{3}{4}$ of the labeled shelf life. Only those bidders shall quote who can manufacture and supply the product with the required shelf life. The product of labeled shelf life lesser than required shelf life will not be accepted. The product should not have such storage condition requiring it to be stored below 2°C.

Quality Assurance: The supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of specifications and related documents (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for

the purpose made; (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per WHO-GMP.

In case of imported items the remaining shelf life of 60% or more may be accepted with an undertaking that the firm will replace the unused expired stores with fresh goods. However, firms supplying drugs with remaining shelf life of 75% or more need not submit such undertaking.

5. The protocol of the tests should include the requirements given in I.P for tablets and those required specifically for the product specifications. The Bidder must submit its Test/ Analysis Report for every batch of drug along with invoice. In case of failure on the part of the supplier to furnish such report, the batch of drugs will be returned back to the supplier and he is bound to replenish the same with approved laboratory test report. The supplier shall provide the validation data of the analytical procedure used for assaying the components and shall provide the protocols of the tests applied and the placebo material when demanded for the purpose of testing.
6. The Drugs and medicines supplied by the successful Bidder shall be of the best quality and shall comply with the specification, stipulations and conditions specified in the Bid documents.
7. If supplies are not fully completed in **60 days** from the date of the Purchase Order (**75 days** for drugs of the category of serum, vaccine, enzymes, blood grouping reagents, biological products, powder for injections and imported drugs), the provisions of liquidated damages of Bid conditions will come into force. The Supplier should supply the drugs at the Warehouse specified in the Purchase Order and if the drugs supplied at a designated places other than those specified in the Purchase Order, transports charges will be recovered from the supplier.
8. **If the supplier fails to execute at least 50% of the quantity mentioned in a purchase order and such part supply is come into existence in three Purchase orders during the currency of contract period, then supplier shall be liable for debarment for the particular product for two years. Two years period will be reckoned from the date of issuance of such debarment order.**

-
9. If the Bidder fails to execute the supply within the stipulated time, the ordering authority is at liberty to make alternative purchase of the items of drugs and medicines for which the Purchase orders have been placed from any other sources (such as Public Sector undertakings at their rates, empanelled bidders, and bidders who have been technically qualified in the said bid) or in the open market or from any other Bidder who might have quoted higher rates at the risk and the cost of the supplier and in such cases the Ordering Authority/Bid inviting authority has every right to recover the cost and impose penalty as mentioned in Clause 19, apart from terminating the contract for the default.
 10. The order stands cancelled after the expiration of delivery period, and if the extension is not granted with or without liquidated damages. Apart from risk/alternate purchase action, the Bidder shall also suffer forfeiture of the performance security and shall invite other penal action like blacklisting/Debarring disqualification from participating in present and future Bids of Bid Inviting Authority/ordering authority. . (As per guidelines for blacklisting/ debarring at annexure- IX including amendment)
 11. It shall be the responsibility of the supplier for any shortage/damage at the time of receipt at the designated places.
 12. If at any time the Bidder has, in the opinion of the ordering authority, delayed in making any supply by reasons of any riots, mutinies, wars, fire. storm, tempest or other exceptional cause, on a specific request made by the Bidder before expiring of supply period, the time for making supply may be extended by the ordering authority at its discretion for such period as may be considered reasonable. The exceptional causes do not include the scarcity of raw material, Power cut, labour disputes. Reasons must be beyond control of supplier.
 13. The supplier shall not be in any way interested in or concerned directly or indirectly with, any of the officers, subordinates or servants of the Bid Inviting Authority in any trade or business or transactions nor shall the supplier give or pay promise to give or pay any such officers, subordinates or servants directly or indirectly any money or fee or other considerations under designation of “Customs” or otherwise, nor shall the supplier permit any person or persons

whom so ever to interfere in the management or performance hereof under the power of attorney or otherwise without the prior consent in writing of the Bidder Inviting Authority.

14. If the supplier or any of its approved items gets debarred/banned/blacklisted in any state after entering into agreement with RMSCL, it shall be the responsibility of the supplier to inform RMSCL without any delay about the same.
 - i. In case the Firm is black listed/debarred/banned after submission of bid document, it should inform the RMSCL within 15 days of blacklisting/debarring/banning. If the blacklisted/debarred / banned firm does not inform the RMSCL within stipulated time, a penalty amounting to @ two per cent of purchase orders issued between the date of blacklisting /debarring/banning and the date of informing to RMSCL, both dates inclusive, shall be imposed, subject to a minimum penalty of Rs 20,000 and a maximum penalty up to Rs 2,00,000 only.
 - ii. If it is brought to the notice of RMSCL that the similar drug of the supplier firm has been found spurious / adulterated in any other state (whether the firm / product has been blacklisted/ debarred/ banned or not); then no further purchase orders shall be issued for the product and the rate contract with the firm for the product shall be cancelled.
15. **If a supplier does not supply any quantity against two successive purchase orders then supplier shall be liable for debarment for the particular product for one year. One year period will be reckoned from the date of issuance of such debarment order.**
16. If a supplier fails to execute first order, without proper justification, a show cause notice may be given to him to respond within 7 days. If it does not respond or does not give reasonable justification, the corporation may order to L-2 and L-3, for entire failed supply on L-1 matched rate. If L-2 and L-3 matched rates are not available, then only purchase may be made on 'Risk and cost basis' as being done presently subject to other condition of Bid documents.

17. The supplier of sevoflurane anesthetic (Item code no. 491) shall install vaporizers on loan basis free of cost, in required numbers, as per the need of the Healthcare facilities/ institutions. The installation report of the vaporizers should be submitted along with the invoice.

18. If the supplier fails to execute full supply of the quantity mentioned in a purchase order then a penalty of 15 % of Value of unsupplied quantity shall be charged. Cases of zero supply against a purchase order shall also be dealt with in same manner.

14. **LOGOGRAMS / Markings**

Logogram means, wherever the context occurs, the design as specified below:-

DESIGNS FOR LOGORAMS

Logogram for item code except 448W	Logogram for item code 448W
	

INJECTIONS

Injection in ampoule form should be supplied either in Double constricted neck ampoules or snap off type ampoules with the label bearing the words “Rajasthan Govt. Supply- Not for sale निःशुल्क वितरण हेतु, QC – Passed” overprinted and the following logogram which will distinguish from the normal trade packing. Name of drug should be printed in English and Hindi languages and should be legible and be printed more prominently. Storage directions should be clear, legible, preferably with yellow highlighted background.



The vials should be supplied with aluminum seals containing the following logogram:



LIQUIDS

Liquid preparations should be in bottles with pilfer-proof caps bearing the following logogram:

Logogram for item code except 448W	Logogram for item code 448W and 489B

The top of the cap and the label to be affixed on the containers should bear a distinct colour different from the colour of the label of the trade packs and they should be overprinted in red colour with the words **“Rajasthan Govt. Supply- Not for Sale निःशुल्क वितरण हेतु, QC – Passed”** and the logogram. Name of drug should be printed in English and Hindi languages and should be legible and be printed more prominently. Storage directions should be clear, legible, preferably with yellow highlighted background.



OINTMENTS & CREAMS

Ointments & Creams should be supplied in tubes bearing the following logograms and the words **“Rajasthan Govt. supply- Not for sale निःशुल्क वितरण हेतु, QC – Passed”** overprinted. Name of drug should be printed in English and Hindi languages and should

be legible and be printed more prominently. Storage directions should be clear, legible, preferably with yellow highlighted background.



TABLETS & CAPSULES

Tablets and Capsules should be supplied in Strips or Blisters or as mentioned in the list of items for bid. The strip, etc, should bear the following logograms and the words **“Rajasthan Govt. supply- Not for sale निःशुल्क वितरण हेतु, QC – Passed”** overprinted. Name of drug should be printed in English and Hindi languages and should be legible and be printed more prominently. Storage directions should be clear, legible, preferably with yellow highlighted background.

Logogram for item code except 448W	Logogram for item code 448W and 489B

SPECIMEN LABEL FOR OUTER CARTON

SHALL BE OF DIFFERENT COLOURS FOR DIFFERENT CLASS OF DRUGS

RAJASTHAN GOVT. SUPPLY NOT FOR SALE (Name of Drugs etc.)_____ CONSTITUENTS OF..... Name of the Drug, Manufactured by, Batch no Mfg.Date, Exp. Date, Quantity/Kit Net. Weight:.....Kg Manufactured by/Assembled by

The name of the drug shall be mentioned in Hindi and English and should be legible and be printed more prominently. A uniform colour theme and artwork will be necessary. Apart from this “**For Govt. of Rajasthan – Not for Sale निःशुल्क वितरण हेतु, QC – Passed**” along with logo of RMSCL will be printed on each strip/label of the bottle. The storage directions should be clear, legible and preferably with yellow highlighted background.

1. Bids for the supply for Drugs and medicines etc., shall be considered only if the Bidder gives undertaking in his Bid that the supply will be prepared and packed with the logogram printed on the strips of tablets and capsules and labels of bottles, ampoules and vials etc., as per the design mentioned above.
2. All tablets and capsules have to be supplied in standard packing in aluminum strip or blisters with aluminium foil back with printed logogram and shall also conform to schedule P1 of the Drugs & Cosmetics Act & Rules wherever it applies. Affixing of stickers and rubber stamps shall not be accepted.
3. Labels of Vials, Ampoules and Bottles containing the items Bided for should also carry the logogram.
4. Failure to supply Drugs etc., with the logogram will be treated as breach of the terms of agreement and liquidated damages will be deducted from bills payable as per conditions in Clause 18.2 Bidders who are not willing to agree to conditions above will be summarily rejected.
5. In case of imported drugs affixing rubber stamp on the original label is allowed with indelible ink on inner most and outer packing.

15. PACKING

1. The item shall be supplied in the package schedule given below and the package shall carry the logogram specified in clause -14. The labeling of different packages should be as specified below. The packing in each carton shall be strictly as per the specification mentioned. Failure to comply with this shall lead to non-acceptance of the goods besides imposition of penalties.

2. The pediatric drops should always be supplied with dropper. A measuring cap with suitable markings must be provided for other paediatric oral liquid preparations.
3. The labels in the case of injectables should clearly indicate whether the preparations are meant for IV, IM, SC, etc.
4. Injection vials should have flip off seals.
5. All plastic containers should be made of virgin grade plastic.
6. The name of the drug should be printed in clearly legible bold letters (It is advisable that the colour of font be different from other printed matter to make the name highly conspicuous).
7. It should be ensured that only first hand fresh packaging material of uniform size is used for packing. All packaging must be properly sealed and temper proof.
8. All packing containers should strictly conform to the specifications prescribed in the relevant pharmacopoeia/Act.
9. Packing should be able to prevent damages or deterioration during transit.
10. In the event of items supplied found to be not as per specifications in respect of their packing, the Ordering Authority is at liberty to make alternative purchase of the item for which the purchase orders have been placed from any other sources or from the open market or from any other Bidder who might have quoted higher rates at the risk and the cost of the supplier. In such cases the ordering authority has every right to recover the cost and impose penalty as mentioned in Clause 18.2 and 19.

I. SCHEDULE FOR PACKAGING OF DRUGS AND MEDICINES GENERAL SPECIFICATIONS

No corrugate package should weigh over 15 kgs (i.e. product + inner carton + corrugated box).

All items should be packed only in first hand strong boxes only.

Every corrugated box should preferably be of single joint and not more than two joints.

Every box should be stitched using pairs of metal pins with an interval of two inches between each pair.

The flaps should uniform meet but should not overlap each other. The flap when turned by 45-60 should not crack.

Every box should be sealed with gum tape running along the top and lower opening.

CARRY STRAP:

Every box should be strapped with two parallel nylon carry straps (they should intersect.)

LABEL:

Every corrugated box should carry a large outer label clearly indicating that the product is for “Rajasthan Govt. Supply-Not for Sale”.

The Product label on the cartoon should be large, atleast 15 cms x 10 cms dimension. It should carry the correct technical name, strength or the product, date of manufacturing, date of expiry quantity packed and net weight of the box.

OTHERS:

NO box should contain mixed products or mixed batches of the same product.

II. SPECIFICATION FOR CORRUGATED BOXES HOLDING TABLETS/CAPSULES/PESSARIES

1. The total weight of the box should be approx of 7-8 Kgs.

III. SPECIFICATION FOR LARGE VOLUME BOTTLE i.e., ABOVE 100 ml AND BELOW 1 LIT.

1. All these bottles should be packed only in single row with partition between each and also with top and bottom pad of 3 ply.

IV. SPECIFICATION FOR IV FLUIDS

Each corrugated box may carry maximum of only 24 bottles of 500 ml in a single row or 50 bottles of 100 ml in 2 rows with individual sealed polythene cover and centre partition pad, top and bottom pads of 3 ply.

V. SPECIFICATION FOR LIQUID ORALS

100 bottles of 50 ml or 60 ml may be packed in a single corrugated in 2 rows with top, bottom and centre pad of 3 ply.

50 bottles of 100 ml – 120 ml may be packed in a similar manner in a single corrugated box.

If the bottles are not packed in individual carton, 3 ply partition should be provided between each bottle. The measuring device should be packed individually.

VI. SPECIFICATION FOR OINTMENT/CREAM/GELS PACKED IN TUBES:

No corrugated box should weigh more than 7-8 Kgs.

Every Ointment/Cream/Gel tube should be individually packed in carton and then packed in 20's in a grey board box, which may be packed in a corrugated box.

VII. SPECIFICATIONS FOR INJECTION (IN VIALS AND AMPOULES)

Vials may be packed in corrugated boxes weighing upto 15 Kgs. Ampoules should be packed in C.B weighing not more than 8 Kgs.

In the case of 10 ml Ampoules or 50 ampoules may be packed in a grey board box. Multiples of grey board boxes packed in CB. In case of ampoules larger than 10 ml only 25 ampoules may be packed in a grey board box with partition. If the vial is packed in individual cartoon, there is no necessity for grey board box packing. The individual cartoon may be packed as such in the CB with centre pad.

In case of ampoules every grey board box should carry 5 amps alongwith Cutters placed in a polythene bag.

Vials of eye and ear drops should be packed in a individual cartoon with a dispensing device. If the vial is of FFS/BFS technology, they should be packed in 50's in a grey board box.

Cutters are not required with ampoules in the case of snap off type ampoules.

VIII. SPECIFICATION FOR ORS

Primary Packing:- The pouches/sachets of ORS should be three layered with following composition

Site	Material	Micron	MM	g/m^2
Inner	Polyethylene	50	0.040-0.050	36.9-46.1
Middle	Aluminium	09	0.009-0.015	24.3-40.5
Outside	Polyester	12	0.012-0.015	12.9-20.9

-

Secondary Packages and Tertiary package:-

50 sachets may be packed in grey board boxes and 10 grey board boxes in a C.B.

IX. LYSOL

Not more than four 5 liters cans may be packed in a single Box.

16. QUALITY TESTING

1. Sampling of supplies from each batch will be done at the point of supply or distribution/storage points for testing. (The samples would be sent to different empanelled laboratories for testing by the ordering authority after coding). The RMSCL will deduct a sum of 1.5% from the amount of bill payable to supplier on account of handling and testing charges.
2. The Drugs shall have the active ingredients within the permissible level throughout the shelf life period of the drug. The samples may also be drawn periodically during the shelf life period. The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories. Samples which do not meet quality requirements shall render the relevant batches liable to be rejected. If the sample is declared to be Not of Standard Quality or spurious or adulterated or misbranded, such batch/batches will be deemed to be rejected goods.
3. In the event of the samples of the Drugs and medicines supplied failing quality tests or found to be not as per specification the ordering authority is at liberty to make alternative purchase of items of drugs and medicines for which the Purchase orders have been placed from any other sources or from the open market or from any other Bidder who might have quoted higher rates at the risk and the cost of the supplier and in such cases the ordering authority has every right to recover the cost and impose penalty as mentioned in Clause 19.
4. The supplier shall furnish to the purchaser the evidence of bio-availability and/or bio-equivalence for certain critical drugs when asked for. If there is any problem in the field the B.M.R/B.P.R for the particular batch shall also be supplied when demanded.

5. The products should conform to the standards of IP/BP / USP as the case may be. In case the product is not included in the said compendium, the supplier, upon award of the contract, must provide the reference standards and testing protocols for quality control testing. For imported drugs respective countries pharmacopeia standards shall be acceptable (even if the product is official in IP)
6. The supply of any item shall be considered complete for the purpose of calculation of liquidated damages only when reference standards/ standard testing procedure or test protocol/placebo materials are made available to the corporation along with the supply of items as per the purchase order. However these materials and documents shall be made available by supplier to Quality Cell of RMSCL Headquarter. Such requirement will however be indicated in the purchase order.

17. PAYMENT PROVISIONS

1. No advance payment towards costs of drugs, medicines etc., will be made to the Bidder.
2. On receipt of the prescribed consolidated invoice duly stamped and signed by authorized signatory and analytical laboratory report regarding quality. (Annexure- XII & XIII)
3. The in charge of district drug warehouse (DDW) will acknowledge the drugs received & ensure entry in e- Aushadhi software online. .
4. All bills/ Invoices should be raised in **triplicate** and in the case of excisable Drugs and Medicines; the bills should be drawn as per **GST Rules / other applicable Rules if any** in the name of the authority as may be designated. The supplier will deliver following document at the time of delivery at DDW/**MCDW**.
 - a. In house test report of drug.
 - b. The challan / invoice copy pertaining to DDW/ **MCDW**
5. **Payments for supplies will be considered after receipt of reports of standard quality on samples having been tested by approved laboratories of ordering authority.**
 - (i) **Payments can be initiated if 50 % supply has been made against a purchase order by a supplier before expiry of supply period/extended supply period.**

(ii) After expiry of supply period/extended supply period payments for actual supplies made against a purchase order will be made although supplies are less than 50 %.

6. If at any time during the period of contract, the price of Bided items is reduced or brought down by any law or Act of the Central or State Government or by the Bidder himself, the Bidder shall be bound to inform ordering authority immediately about it. Ordering authority empowered to unilaterally effect such reduction as is necessary in rates in case the Bidder fails to notify or fails to agree for such reduction of rates.

In case the price of a drug fixed by NPPA (Govt of India) under applicable DPCO is less than the RMSCL contract price, the supplier shall be bound to make the supplies of such items at price fixed by the Govt.

- 7(a) In case of any enhancement in **GST as per** notification of the Government after the date of submission of Bids and during the Bid period, the quantum of additional **GST** so levied will be allowed to be charged extra as a separate item without any change in the basic of the price structure price of the Drugs approved under the Bid. For claiming the additional cost on account of the increase in **GST**, the Bidder should produce a letter from the concerned Excise authorities / **GST authorities (Central and State)** for having paid additional **GST** on the goods supplied to ordering authority and also must claim the same in the invoice separately. **In case of reduction in rates of GST price will be reduced accordingly.**

Similarly if there is any reduction in the rate of essential drug, as notified by the Govt. **(Including NPPA)**, after the date of submission of Bid, the quantum of the price to the extent of reduction of essential drug will be deducted without any change in the basic price of the price structure of the drugs approved under the Bid.

- 7(b) In case of successful bidder has been enjoying **GST** exemption **or** any criteria of Turnover etc., such bidder will not be allowed to claim **GST** at later point of time, during the tenure of contract, when the **GST** is chargeable on goods manufactured/**Supplied**.

8. (i) If the supplier requires an extension in time for completion of contractual supply, on account of occurrence of any hindrance he shall apply in writing for extension on occurrence of hindrance but not after the stipulated date of completion of supply.
- (ii) The purchase Officer may extend the delivery period with or without liquidated damages in case they are satisfied that the delay in the supply of goods is on account of hindrances. Reasons shall be recorded.
- (iii) **Extension in delivery period:-** In case of extension in the delivery period with liquidated damages the recovery shall be made on the basis of following percentages of value of stores which the Bidder has failed to supply:-
- a) Delay upto one fourth period of the prescribed delivery period; 2.5%
 - b) Delay exceeding one fourth but not exceeding half of the prescribed delivery period; 5%
 - c) Delay exceeding half but not exceeding three fourth of the prescribed delivery period; 7.5%
 - d) Delay exceeding three fourth of the prescribed delivery period; 10%
- Note 1:-** Fraction of a day in reckoning period of delay in supplies shall be eliminated if it is less than half a day. The maximum amount of liquidated damages shall be 10%.
- Note 2:-** In specific condition, permission for additional delay of 10 days may be granted for supply, in such a case an additional penalty of 5% shall be levied.
- Note 3:-** If a supplier seeks extension in supply period beyond two times the time indicated in purchase order, the supply period shall be extended with the condition that if the rate received in new bid(s) invited are lower than the rate contract in operation, then the supplier shall be entitled to the lower rates so received.
9. If, at any time during the continuance of this Agreement, the Supplier has, in the opinion of the Purchaser, delayed in making any supply ordered, by the reasons of any riots, mutinies, wars, fire, storm, tempest or other exceptional cause, on a specific request made by the Supplier before expiry of supply period indicated in P.O , the time for effecting delivery may be extended by the Purchaser surely at

his discretion for such period as may be considered reasonable by the Purchaser.

No further representation from the Supplier will be entertained on this account.

10. If the firm is Blacklisted/Debarred by State Govt. of Rajasthan during rate contract period/ after rate contract period, the firm has to follow below mentioned conditions:-

- Further Purchase orders should not be placed to firm.
- Purchase orders in process shall be cancelled.
- All unconsumed stock from DDWs should be lifted on the cost of firm.
- If payment is made for unconsumed stock it should be recovered from firm.
- All rate contracts should be cancelled.

18. DEDUCTION IN PAYMENTS:

1. If the supply is received in damaged conditions it shall not be accepted.
2. All the Bidder are required to supply the product with logogram and with prescribed packing specification. If there is any deviation in these Bid conditions a separate damages will be levied @ 2% irrespective of the ordering authority having actually suffered any damage/loss or not, without prejudice the rights of alternative purchase specified in Clause **No.15.10.**

19. QUALITY CONTROL DEDUCTION & OTHER PENALTIES:

1. If the successful Bidder fails to execute the agreement and/or to deposit the required performance security within the time specified or withdraws his Bid after the intimation of the acceptance of his Bid has been sent to him or owing to any other reasons, he is unable to undertake the contract, his contract will be cancelled and the Bid security Deposit deposited by him along with his Bid, shall stand forfeited by the Bid Inviting Authority and he will also be liable for all damages sustained by the Bid Inviting Authority apart from blacklisting/ debarring the supplier. (As per guidelines for blacklisting/ debarring at annexure IX)
2. (i) If the samples drawn from supplies do not conform to statutory standards, the supplier will be liable for relevant action under the existing laws and the entire stock in such batch should be taken back by the supplier within a period of 30 days from the issue of letter from ordering authority the information of which

may be communicated by e- mail. The stock shall be taken back at the expense of the supplier. Ordering authority has the right to destroy such NOT OF STANDARD DRUGS IF THE SUPPLIER does not take back the goods within the stipulated time. Ordering authority will arrange to destroy the NOT OF STANDARD drugs within 90 days after the expiry of 30 days mentioned above, without further notice, and shall also collect demurrage charge calculated @ 2% per week on the value of the drugs rejected till such destruction.

The Supplier shall replace the stock of NOSQ goods with fresh goods upon intimation to do so by the ordering authority.

(ii) If RMSCL decides not to return the NOSQ drugs to supplier and decides to destroy NOSQ drugs at its level, then provision of demurrage charge will not apply. Means, if RMSCL writes to supplier to take back NOSQ drugs, then demurrage provision as per 19(2)(i) will be applied and if does not write to take back and decides to destroy drugs at its own level, then demurrage charge provision as per 19(2)(i) will not be applied.

3. The supplier will not be entitled to any payment whatsoever for Items of drugs found to be of NOT OF STANDARD QUALITY whether consumed or not consumed and the ordering authority is entitled to deduct the cost of such batch of drugs from the any amount payable to the Bidder. On the basis of nature of failure, the product/supplier will be moved for Black Listing. (As per guidelines for blacklisting/ debarring at annexure IX including amendment)
4. For supply of drugs of NOT OF STANDARD QUALITY the respective Drugs Controller will be informed for initiating necessary action on the supplier and that the report of product shall be sent to the committee for appropriate action including blacklisting. (As per guidelines for blacklisting/ debarring at annexure IX)
5. The decision of the ordering authority or any Officer authorized by him as to the quality of the supplied drugs, medicines etc., shall be final and binding.
6. Ordering Authority will be at liberty to terminate without assigning any reasons thereof the contract either wholly or in part on 30 days notice. The Bidder will not be entitled for any compensation whatsoever in respect of such termination.

7. For infringement of the stipulations of the contract or for other justifiable reasons, the contract may be terminated by the ordering authority, and the supplier shall be liable for all losses sustained by the ordering authority, in consequence of the termination which may be recovered personally from the supplier or from his properties, as per rules.
8. Non performance of any contract provisions shall be examine and may disqualify the firm to participate in the future Bids.
9. **In the event of making ALTERNATIVE PURCHASE, as specified in Clause 13.10, Clause 15.10 and in Clause 16.3 the penalty will be imposed on supplier apart from forfeiture of Security Deposit. The excess expenditure over and above contracted process incurred by the ordering authority in making such purchases from any other sources or from the open market or from any other Bidder who has quoted higher rates and other losses sustained in the process, shall be recovered from the performance security or from any other money due and become due to the supplier and in the event of such amount being insufficient, the balance will be recovered personally from the supplier and provided further that such amount to be levied as per penalty from supplier on account of non-supply shall not be less than 15% of the value of non-supplied even when rates in alternative purchase method are lower / equivalent to rates in original tender.**
10. In all the above conditions, the decision of the Bid Inviting Authority, viz Managing Director, Rajasthan Medical Services Corporation Ltd, would be final and binding; in case of any dispute regarding all cases under Bid procedure or in any other non-ordinary situation and would be acceptable to all.
11. All litigations related to the supplier for any defaults will be done by Bid Inviting Authority and his decision will be final and binding.
12. In the case of litigation as per court decision/award by arbitrator, if any amount of interest is payable/receivable etc. then RMSCL will charge interest@9% per annum simple interest and it will be payable @ 6% per annum simple interest only.

20. EMPANELMENT OF BIDDERS (MANDATORY)

Bidders which are found eligible / responsive on technical grounds / criteria would be empanelled for those item for which they have bided in the NIB as per Annexure VIII. Empanelment is mandatory for all eligible firms / bidders. A fee of Rs 5900 (including GST @18%) is to be submitted along with bid for empanelment. The empanelment would entitle a firm to participate in RMSCL's limited bids. Such situations may normally arise when the open bid for a Drugs & Medicines fails and there is an urgency to purchase it, or when the L-1 bidder has fail to supply or the rate contract of an item ceases to exist for any reason. The Bidder has to submit an undertaking in the format given at Annexure-XI.

The empanelment can be renewed for the next one year term on payment of the empanelment fee as applicable at the time of renewal.

It is clarified that all bidders are require to submit Empanelment fees which is valid for one financial year. Those bidders who have already submitted Empanelment fees in previous bid (NIB-13/2022, NIB-14/2022, NIB-15/2022, NIB-16/2022 and NIB-17/2022), they need not submit Empanelment fees .

21. SAVING CLAUSE

No suit, prosecution or any legal proceedings shall lie against Bid Inviting Authority or any person for anything that is done in good faith or intended to be done in pursuance of Bid.

22. JURISDICTION

(1) In the event of any dispute arising out of the Bid or orders such dispute would be subject to the jurisdiction of the Courts of Jaipur or Honorable High Court (Jaipur Bench **only**).

(2) If approved bidder suffers by any decision or act or interpretation of procuring entity, he may request for appointment of a Sole Arbitrator to decide the issue. Fees and other charges shall be borne by both parties equally.

23. CORRECTION OF ARITHMETIC ERRORS:

Provided that a financial bid is substantially responsive, the procuring Entity will correct arithmetical errors during evaluation of Financial Bids on the following basis:

- (i) If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail and the total price shall be corrected, unless in the opinion of the Procuring Entity there is an obvious misplacement of the decimal point in the unit price, in which case the total price as quoted shall govern and the unit price shall be corrected;
- (ii) If there is an error in a total corresponding to the addition or subtraction of subtotals, the subtotals shall prevail and the total shall be corrected; and.
- (iii) If there is a discrepancy between words and figures, the amount in words shall prevail, unless the amount expressed in words is related to an arithmetic error, in which case the amount in figures shall prevail subject to clause (a) and (b) above.

If the Bidder that submitted the lowest evaluated bid does not accept the correction of errors, its Bid shall be disqualified and its Bid Security shall be forfeited or its Bid Securing Declaration shall be executed.

24. PROCURING ENTITY'S RIGHT TO VARY QUANTITY:

- (i) At the time of award of contract, the quantity of Drugs, originally specified in the bidding documents may be increased or decreased. There will not be any minimum quantity guaranteed against bid quantity. The bid quantity is only indicative. Actual purchase can be more or less than the bid quantity based on actual consumption in the hospitals during Rate Contract period.

The supplier shall submit the supply commitment quantity'' in Annexure **VII at point no. 3** which will be used for the cases where the actual purchase quantity tends to increase substantially from the bid quantity.

- (ii) If the procuring entity does not procure any subject matter of procurement or procures less than the quantity specified in the bidding

documents due to change in circumstances, the bidder shall not be entitled for any claim or compensation except otherwise provided in the conditions of contract.

- (iii) However a bidder is bound to supply up to quantity indicated in bid document, considering the total production capacity & capacity dedicated to RMSCL. Moreover, the actual purchases beyond Bid quantity may be made keeping in view the supply commitment of bidder to corporation.

25. DIVIDING QUANTITIES AMONG MORE THAN ONE BIDDER AT (IN CASE OF PROCUREMENT OF GOODS):

The bid quantity shall be fixed in following manner-

L-1(Single Bidder)100%

Between L-1 and Rate Matched Firm-1in the ratio of 60:40

Among L-1, Rate Matched Firm-1 and 2in the ratio of 50:25:25

Purchase preference shall be given to MSME's unit of Rajasthan as per notification of Finance (GF&AR Division) Department; Government of Rajasthan notification S.O.165 dated 19.11.2015).

The supply orders for quantity fixed as above may be issued as and when required. RMSCL has full rights to increase or decrease the bid quantity upto any limit during the contract period.

26. GRIEVANCE REDRESSAL DURING PROCUREMENT PROCESS:

The Designation and address of the First Appellate Authority is ***Special Secretary*** / Secretary, Medical, Health & Family Welfare, Govt. of Rajasthan.

The Designation and address of the Second Appellate Authority is Principal Secretary, Medical, Health & Family Welfare, Govt. of Rajasthan and Chairman, RMSCL.

i. Filling an appeal

If any Bidder or prospective bidder is aggrieved that any decision, action or omission of the Procuring Entity is in contravention to the provisions of the Act or the Rules of the Guidelines issued there under, he may file an appeal to First Appellate Authority, as specified in the Bidding Document within a period of ten days from the date of such decision or action,

omission, as the case may be, clearly giving the specific ground or ground on which he feels aggrieved:

Provided that after the declaration of a Bidder as successful the appeal may be filed only by a Bidder who has participated in procurement proceedings:

Provided further that in case a Procuring Entity evaluates the Technical Bids before the opening of the Financial Bids, an appeal related to the matter of Financial Bids may be filed only by a Bidder whose Technical Bid is found to be acceptable.

ii. The Officer to whom an appeal is filed under Para (1) shall deal with the appeal as expeditiously as possible and shall Endeavour to dispose it of within thirty days from the date of the appeal.

iii. If the officer designated under Para (1) fails to dispose of the appeal filed within the period specified in Para (2), or if the Bidder or prospective bidder or the Procuring Entity is aggrieved by the order passed by the First Appellate Authority, the Bidder or prospective bidder or the Procuring Entity, as the case may be, may file a second appeal to second Appellate Authority specified in the Bidding Document in this behalf within fifteen days from the expiry of the period specified in Para (2) or of the date of receipt of the order passed by the First Appellate Authority, as the case may be.

iv. Appeal not to lie in certain cases

No appeal shall lie against any decision of the Procuring Entity relating to the following matters, namely:-

- (a) Determination of need of procurement;
- (b) Provision limiting participation of Bidders in the Bid process; (c) The decision of whether or not to enter into negotiations;
- (d) Cancellation of a procurement process;
- (e) Applicability of the provisions of confidentiality.

v. Form of Appeal

(a) An appeal under Para (1) or (3) above shall be in the annexed Form along with as many copies as there are respondents in the appeal.

(b) Every appeal shall be accompanied by an order appealed against, if any, affidavit verifying the facts stated in the appeal and proof of payment of fee.

(c) Every appeal may be presented to First Appellate Authority or Second Appellate Authority, as the case may be, in person or through registered post or authorised representative.

vi. Fee for filling appeal

(a) Fee for first appeal shall be rupees two thousand five hundred and for second appeal shall be rupees ten thousand, which shall be non-refundable.

(b) The fee shall be paid in the form of bank demand draft or banker's cheque of a Scheduled Bank in India payable in the name of Appellate Authority concerned.

vii. Procedure for disposal of appeal

(a) The First Appellate Authority or Second Appellate Authority, as the case may be, upon filling of appeal, shall issue notice accompanied by copy of appeal, affidavit and documents, if any, to the respondents and fix date of hearing.

(b) On the date fixed for hearing, the First Appellate Authority or Second Appellate

Authority, as the case may be, shall,-

(i) Hear all the parties to appeal present before him; and

(ii) Peruse or inspect documents, relevant records or copies thereof relating to the matter.

(c) After hearing the parties, perusal or inspection of documents and relevant records or copies thereof relating to the matter, the Appellate Authority concerned shall pass an order in writing and provide the copy of order to the parties free of cost.

(d) The order passed under sub-clause (c) above shall be placed on the State Public procurement Portal.

27. COMPLIANCE WITH THE CODE OF INTEGRITY AND NO

CONFLICT OF INTEREST:

Any person participating in a procurement process shall-

- a) Not offer any bribe, reward or gift or any material benefit either directly or indirectly in exchange for an unfair advantage in procurement process or to otherwise influence the procurement process;
- b) Not misrepresent or omit misleads or attempts to mislead so as to obtain a financial or other benefit or avoid an obligation;
- c) Not indulge in any collusion, Bid rigging or any-competitive behaviour to impair the transparency, fairness and progress of the procurement process;
- d) Not misuse any information shared between the procuring Entity and the Bidders with an intent to gain unfair advantage in the procurement process;
- e) Not indulge in any coercion including impairing or harming or threatening to do the same, directly or indirectly, to any part or to its property to influence the procurement process;
- f) Not obstruct any investigation or audit of a procurement process;
- g) Disclose conflict of interest, if any; and
- h) Disclose any previous transgressions with any Entity in India or any other country during the last three years or any debarment by any other procuring entity.

Conflict of interest:-

The Bidder participating in a bidding process must not have a Conflict of Interest.

A Conflict of interest is considered to be a situation in which a party has interests that could improperly influence that party's performance of official duties or responsibilities, contractual obligations, or compliance with applicable laws and regulations.

I. A Bidder may be considered to be in Conflict of interest with one or more parties in bidding process if, including but not limited to:

- a. Have controlling partners/shareholders in common; or
 - b. Receive or have received any direct or indirect subsidy from any of them;
- or

- c. Have the same legal representative for purposes of the Bid; or
- d. Have a relationship with each other, directly or through common third parties, that puts them in a position to have access to information about or influence on the Bid of another Bidder, or influence the decisions of the Procuring Entity regarding the bidding process; or
- e. The Bidder participates in more than one Bid in a bidding process. Participation by a Bidder in more than one Bid will result in the disqualification of all Bids in which the Bidder is involved. However, this does not limit the inclusion of the same subcontractor, not otherwise participating as a Bidder, in more than one Bid; or
- f. The Bidder or any of its affiliates participated as a consultant in the preparation of the design or technical specification of the Goods, Works or Services that are the subject of the Bid; or
- g. Bidder or any of its affiliates has been hired (or is proposed to be hired) by the Procuring Entity as engineer-in-charge/ consultant for the contract.

28. FALL CLAUSE

The prices under a rate contract shall be subject to price fall clause. If the rate contract holder quotes / reduces its price to render similar goods, works or services at a price lower than the rate contract price to anyone in the State at any time during the currency of the rate contract, the rate contract price shall be automatically reduced with effect from the date of reducing or quoting lower price, for all delivery of the subject matter of procurement under that rate contract and the rate contract shall be amended accordingly. The firms holding parallel rate contracts shall also be given opportunity to reduce their price by notifying them the reduced price giving them fifteen days time to intimate their acceptance to the revised price. Similarly, if a parallel rate contract holding firm reduces its price during currency of the rate contract, its reduced price shall be conveyed to other

parallel rate contract holding firms and the original rate contract holding firm for corresponding reduction in their prices. If any rate contract holding firm does not agree to the reduced price, further transaction with it, shall not be conducted.

29. **APPLICABILITY OF RULES**

Besides above conditions the provisions of RTPP Act 2012 & RTPP Rules 2013 will be applicable.

**Managing Director
Rajasthan Medical Services Corporation Ltd**

ANNEXURE-I

CAUTION : USE "FCMBR" MENU OPTION IN FINACLE INSTEAD OF "TM"

Bank Copy

punjab national bank

DIST. NO.

Branch

Institute Name

Rajasthan Medical Services Corporation, Jaipur

Institute ID

RMSCJ - A/c No. 2246002100024414

Date of Deposit

DD MM YY

DETAILS OF THE SUPPLIER

Supplier Name

Tender Ref. No.

Type of Deposit

Select any one out of - Tender Fees/EMD/SD/Tender Processing Fees/Others

Mobile No.

Cash Deposit:

Denomination	₹	Ps
1000 *		
500 *		
100 *		
50 *		
20 *		
10 *		
5 *		
Coins *		
Total		

Cheque Deposit:

Chq No	Date of Chq	Name of Bank	₹	Ps

Total fee payable ₹

Commission ₹

Total amount ₹

0	0	0	0	0	0
---	---	---	---	---	---

Amount (in words): ₹

Name of the Depositor

Signature

Address for communication

For Bank use only

Acknowledgement

Cashier/Officer

Customer Copy

punjab national bank

DIST. NO.

Branch

Institute Name

Rajasthan Medical Services Corporation, Jaipur

Institute ID

RMSCJ - A/c No. 2246002100024414

Date of Deposit

DD MM YY

DETAILS OF THE SUPPLIER

Supplier Name

Tender Ref. No.

Type of Deposit

Select any one out of - Tender Fees/EMD/SD/ Tender Processing Fees/Others

Mobile No.

Cash Deposit:

Denomination	₹	Ps
1000 *		
500 *		
100 *		
50 *		
20 *		
10 *		
5 *		
Coins *		
Total		

Cheque Deposit:

Chq No	Date of Chq	Name of Bank	₹	Ps

Total fee payable ₹

Commission ₹

Total amount ₹

0	0	0	0	0	0
---	---	---	---	---	---

Amount (in words): ₹

Name of the Depositor

Signature

Address for communication

For Bank use only

Acknowledgement

Cashier/Officer

Form A

**Application by MSME for price preference or Purchase Preference
or both in Procurement of Goods**

To,
The General Manager
DIC, District.....

1. Name of Applicant with Post
2. Permanent Address
3. Contact Details
 - a) Telephone No.:
 - b) Mobile no. :
 - c) Fax no.:
 - d) Email Address:
4. Name of micro & small enterprise:
5. Office Address:
6. Address of Work Place:
7. No. & Date of Entrepreneurs Memorandum-II/Udyog Aadhaar Memorandum
(enclose photo copy)
8. Products for which Entrepreneurs Memorandum-II/ Udyog Aadhaar
Memorandum availed:
9. Products for which are at present being produced by the enterprise:
10. Products for which price preference or Purchase preference or both has been
applied for:
11. Production capacity as per Capacity Assessment Certificate
(enclose photocopy of Capacity Assessment Certificate)

Serial No	Product	Production Capacity	
		Quantity	Value
1			
2			
3			
4			

12. List of Plant & Machinery installed

Serial No	Name of Plant & Machinery	Quantity	Value
1			
2			
3			

13. List of Testing Equipments installed

Serial No	Name of Plant & Machinery	Quantity	Value
1			
2			
3			
4			

14. Benefits availed as per price preference certificate in last financial year and current financial year

a. Benefits depositing Bid Security and Performance Security:

Last financial year			Current financial year	
Departments	Bid Security	Performance Security	Bid Security	Performance Security

b. Details of Supply orders received:

Last financial year				Current financial year		
Departments	No. & Date of purchase order	Amount for which purchase order received	Amount of goods supplied	No. & Date of purchase order	Amount for which purchase order received	Amount of goods supplied

I declare that the above all facts given in the application are correct and my enterprise is producing the items mentioned in column No. 10

Date

Signature
(Name of the applicant
along with seal of post)

-

CERTIFICATE

(See clause 10)

File no. _____

Date _____

It is certified that M/s _____ was
inspected by _____ on dated
_____ and the facts mentioned by the enterprise are
correct as per the record shown by the applicant. The enterprise is eligible for
Price Preference or Purchase Preference or both under this notification. The
certificate is valid for one year from the date of its issue .

Office Seal

Signature
(Full Name of the Officer)
General Manager
District Industries Centre
Rubber Seal/Stamp

Enclosure- (1) Application

(2)

(3)

Form-‘B’
Format of Affidavit
(On Non Judicial Stamp Paper of Rs. 10/-)

I.....S/o.....Age.....Yrs.....
residing at.....Proprietor/Partner/Director of
M/s.....do hereby solemnly affirm and declare that:

(a) My/Our above noted enterprises M/s..... has been
issued acknowledgement of Entrepreneurial Memorandum Part-II by the
Districts Industries Center.....The acknowledgement No.
is.....dated.....and has issued for Manufacture of
following items.

- (i)
- (ii)
- (iii)
- (iv)
- (v)

(b) My/Our above noted acknowledgement of Entrepreneurial Memorandum
Part-II has not been cancelled or withdrawn by the Industries Department and
that the enterprise is regularly manufacturing the above items.

(c) My/Our enterprise is having all the requisite plant and machinery and is
fully equipped to manufacture the above noted items.

Place.....

Signature of Proprietor/Director
Authorized Signatory with Rubber
Stamp and date

VERIFICATION

I.....S/o.....Aged.....Yrs
.....residing
at.....Proprietor/Partner/Director of
M/s.....verify and confirm that the contents at (a), (b) &
(c) above are true and correct to the best of my knowledge and nothing has
been concealed therein. So help me God.

DEPONENT

-
ANNEXURE-III
Ref. Clause No. 5 (m)

ANNUAL TURN OVER STATEMENT

The Annual Turnover (*for drugs and medicines including Surgical and sutures Business*) of M/s. _____ for the past three years are given below and certified that the statement is true and correct.

S.No.	Years	Turnover in Crore (INR.)
1	2018-19	
2	2019-20	
3	2020-21	
Total		Rs. Crore
Average turnover per annual		Rs. Crore
OR		
S.No.	Years	Turnover in Crore (INR.)
1	2019-20	
2	2020-21	
3	2021-22	
Total		Rs. Crore
Average turnover per annual		Rs. Crore

Date:

Seal:

Signature of Auditor/
Chartered Accountant
(Name in Capital)

AGREEMENT

This Deed of Agreement is made on this _____ day
of

_____ 2023 by M/s. _____
represented by its Proprietor/Managing partner/Managing Director having its
Registered _____ Office _____ at
_____ and its Factory
Premises _____ at

(hereinafter referred to as “Supplier” which term shall include its successors, representatives, heirs, executors and administrators unless excluded by the Contract) on one part and Rajasthan Medical Services Corporation Ltd, represented by its Executive Director (P) having is office at Swasthya Bhawan, Tilak Marg, C-Scheme, Jaipur (hereinafter referred to as “The Purchaser” which term shall include its successors, representatives, executors assigns and administrator unless excluded by the Contract) on the other part.

Where as the Supplier has agreed to supply to the Purchaser, the Drugs and Medicines with specifications mentioned in the Schedule attached here to at the prices noted there in and in the manner and under the terms and conditions here in after mentioned and where as the Supplier has deposited with the Purchaser a sum of Rs _____ (Rupees only) as Performance Security for the due and faithful performance of this Agreement, to be forfeited in the event of the Supplier failing duly and faithfully to perform it. Now these presents witness that for carrying duly and faithfully to perform it. Now these presents witness that for carrying out the said Agreement in this behalf into execution the Supplier and the Purchaser do hereby mutually covenant, declare, contract and agree each of them with the other of them in the manner following, that is to say,

1. The term “Agreement”, wherever used in this connection, shall mean and include the terms and conditions contained in the invitation to E-

-

Bid floated for the rate contract cum supply for Drug & Medicines For Rajasthan Medical Services Corporation Ltd, (Rate Contract for the period ending on 31.12.2023) (F.02(368)/RMSCL/PROCUREMENT/DRUG/NIB-01/2023/50 Dated:- 06.01.2023) and technical bid opened on 31.01.2023 the instruction to Bidders, the conditions of Bid, acceptance of Bid, particulars hereinafter defined and those general and special conditions that may be added from time to time.

2. (a) The Agreement is for the supply by the Supplier to the Purchaser of the Drug and Medicines specified in the agreement on the terms and conditions set forth in the Agreement.
7. (b) This Agreement shall be deemed to have come into force with effect from the date of issuance of letter of acceptance no.and dated.....and it shall remain in force up to **31.12.2023** and extendable upto 3 months, if required. Firm shall be bound to accept the extension period of Rate Contract.
- (c) The Bid quantity noted against each item in the schedule attached hereto indicates only the probable total requirements of the Purchaser in respect of each item for the Agreement Period indicated in Clause (b) above. This quantity may increase or decrease at the discretion of the Purchaser. The Supplier shall make supplies of the Drugs and Medicines on the basis of the Purchaser Orders placed on him from time to time by the ordering Authorities of the purchaser specifying the quantities required to be supplied required to be supplied at the specific location in the state of Rajasthan.

TERMINATION OF CONTRACT ON BREACH OF CONDITION

- 1 (a) In case the Supplier fails or neglects or refuse to faithfully perform any of the Covenants on his part herein contained, it shall be lawful for the Purchaser to forfeit the amount deposited by the Supplier as PERFORMANCE SECURITY and cancel the Contract.
- (b) In case the Supplier fails, neglects, or refuse to observe, perform, fulfill and keep, all or any one or more or any part of any one of the Covenants, stipulation and provisions herein contained, it shall be lawful for the Purchaser

-
on any such failure, neglect or refusal, to put an end to this Agreement and thereupon every article, cause and thing herein contained on the part of the Purchaser shall cease and be void, and in case of any damage, loss, expenses, difference in cost or other moneys from out of any moneys for the time being payable to the Supplier under this and/or any other Contract and in case such last mentioned moneys are insufficient to cover all such damages, losses, expenses, difference in cost and other moneys as aforesaid, it shall be lawful for the Purchaser to appropriate the Performance Security made by the Supplier as herein before mentioned to reimburse all such damages, losses, expenses, difference in cost and other money as the Purchaser shall have sustained, incurred or been put to by reason of the Supplier having been guilty of any such failure, negligence or refusal as aforesaid or other breach in the performance of this Contract.

(c) If at any time during the course of the Contract, it is found that any information furnished by the Supplier to the Purchaser, either in his Bid or otherwise, is false, the Purchaser may put an end to the Contract/Agreement wholly or in part and thereupon the provisions of Clause (a) above shall apply.

- 2 The Purchaser reserves the right to terminate without assigning any reasons therefore the Contract/Agreement either wholly or in part without any notice to the Supplier. The Supplier will not be entitled for any compensation whatsoever in respect of such termination of the Contract/Agreement by the Purchaser.

NOTICE ETC, IN WRITING

- 3 All Certificates or Notice or orders for time or for extra, varied or altered supplies which are to be the subject of extra or varied charges whether so described in the Agreement or not, shall be in writing, and unless in writing, shall not be valid, bidding or be of any effect whatsoever.

SUPPLIERS NOT HAVE ANY INTEREST IN THE OFFICERS CONCERNED AND SUBORDINATES

- 4 The Supplier shall not be in any way interested in or concerned directly or indirectly with, any of the Officers, Subordinate or Servants of the Purchaser. In any trade, business or transactions nor shall the Supplier give or pay or promise to give or pay any such Officer, Subordinate or Servant directly or

-

indirectly any money or fee or other consideration under designation of “Custom” or otherwise; nor shall the Supplier permit any person or persons whomsoever to interfere in the management or performance hereof under power of attorney or otherwise without the consent in writing the consent in writing of the Purchaser obtained in first hand.

BANKRUPTCY OF THE SUPPLIER

5 In case the Supplier at any time during the continuance of the Contract becomes bankrupt or insolvent or commits any act of bankruptcy or insolvency under the provisions of any law in that behalf for the time being in force, or should compound with his creditors, it shall be lawful for the Purchaser to put an end to the Agreement, and thereupon every article, clause and thing herein contained to be operative on the part of the Purchaser, shall cease and be void and the Purchaser shall have all the rights and remedies given to him under the preceding clauses.

SERVING OF NOTICE ON SUPPLIER

- 6 All notice or communication relating to or arising out of this Agreement or any of the terms thereof shall be considered duly served on or given to the Supplier if delivered to him or left at his premises, place of business or abode.
- 7 And it is hereby agreed and declared between the parties hereto that in case any question of dispute arises touching the construction or wording of any of clause herein contained on the rights, duties, liabilities of the parties hereto or any other way, touching or arising out of the presents, the decision of the Managing Director, Rajasthan Medical Services Corporation Ltd in the matter shall be final and binding.
- 8 All disputes arising out of this agreement and all questions relating to the interpretation of this agreement shall be decide by the Govt. and the decision of the Govt. shall be final.

SUPPLIER (Signature, Name
& Address With Stamp)

EXECUTIVE DIRECTOR (P),
RAJASTHAN MEDICAL SERVICES CORPORATION LTD.

Witness (Signature, Name & Address)

Witness

1.

1.

2.

2.

Check List

Section	Details of requirement	Document Type	Yes/No If Yes Page No.
A	BID SECURITY DEPOSIT, RISL Fess, Bid Processing Fees, Empanelment Fees.	Challan/DD/ e–deposit generated receipt of Bid Security Deposit, bid fee, RISL fee, empanelment fee and SSI certificate for exemption with Annexure-II	
B	Technical documents	Manufacturing Licence/loan licence	
		Manufacturing Licence renewal /validity certificate	
		Non Conviction Certificate issued by the Drugs Controller	
		WHO-GMP Certificate	
		Import License, if imported.	
		Sale License, in the case of imported drugs	
		Copy of record of import to establish 3 years market standing, if imported.	
		Product Permissions by the Licensing Authority for each and every product quoted	
		Market Standing Certificate issued by the licensing Authority	
		Annexure-VI Check List Of Details Regarding Products Quoted	
C	Other Documents	Documentary evidence for the constitution of the company / concern	
		The instruments such as power of attorney resolution of board etc	
		Copies of balance sheet & profit loss account for three years	
		<u>GST Registration & Proof of GST Return</u>	
		Copy of PAN	
		Annual Turnover Statement	
		Annexure-VII Declaration and Undertaking	
		Annexure-XI Undertaking For Empanelment	

Check list of details regarding products quoted

Product permission as per condition no. 5 (c) and Market Standing as per condition 5 (g)

S. No.	Quoted Item /Code no.	Product permission on enclosed on page no.	Date of product permission / Approval	Product permission of formulation Generic / Branded	Specification as per Code no. Yes/ No	As per MSC product Mfg & Mkt since last 3 years		
						Page No.	Yes/ No	Date of Issue
1								
2								
3								
4								
5								

Declaration & Undertaking

(For F.02(368)/RMSCL/PROCUREMENT/DRUG/NIB-01/2023/50 Dated:- 06.01.2023)

(On Non-Judicial Stamp Paper of Rs 500/-)

I Name.....S/o.....Age.....Prop./Partner/Director/Power
of attorney holder of firm M/s.....situated at (Complete
address of Mfg. unit).....bearing drug
license on Form 25, 28, 10 etc bearing Number.....
&.....respectively, issued on
dated.....valid/Renewed up to.....do here by declare
on oath as follows:-

1. That none of the quoted Drug and Medicines manufactured / imported by us since grant of above drug license have been found as of spurious or adulterated quality and no case in this regard is pending in any court.
2. That the quoted product is manufactured/imported by us, and none has been declared as “Not of standard quality” during last two years.
3. That we have following Commitment of quantity in our plant at above address:-[Ref. Clause No. 24]

S. No.	Quoted item Code No. & Name of Drugs	Monthly Capacity in all shifts in nos.	Annual Production Capacity	Monthly supply Commitment to RMSCL in nos.(Not Less than 10% off estimated bid quantity)	Supply Commitment quantity during rate contract period (not be less than estimated bid quantity)	Estimated Bid Quantity as per Annexure VIII	<u>GSTIN Number & Name of State where GSTIN registered</u>
1.							
2.							

4. That concern/company/firm does not stand blacklisted/banned/debarred on any ground by Bid Inviting Authority or Govt. of Rajasthan or its departments on the date of bid submission. The concern/company/firm does not stand blacklisted/banned/debarred on the ground of conviction by court of law or the products being found spurious or adulterated by any other State /Central Government or it's any agencies (central Drugs procurement agencies). **But my firm is blacklisted/banned/debarred on a different ground by a**

-

procurement agency, the details of which are given below-----
----- (Write 'NIL' if no such matter exists)

5. That our Firm/Company and its Proprietor/Partner/Directors/ Power of attorney holders have not been convicted for contravention of any provisions of Drugs & Cosmetic Act 1940 and rules made there under since grant of license.
6. That we have been granted product permission by the State Licensing Authority for manufacture of quoted products as per the details given below:-

S. No.	Code No.	Name of the Product	Date of product permission obtained from the Licensing Authority	Whether Endorsement is in Generic or Trade Name	Issuing Licensing Authority	Own manufacturing / Loan Licensee (Please mention)	Drug manufacturing/Import License Number for quoted items
1.							
2.							

7. That we have over three years' experience in the manufacture of the quoted product, or the quoted imported product has over 3 years market standing.
8. That we have approved qualified staff, machines & equipments along with capacity to manufacture above category of drugs and our unit have been issued **WHO-GMP*** by Licensing Authority vide letter No.....dated.....valid upto.....
9. That we hereby confirm that we have deposited all the VAT/Sale Tax/**GST & filling returns as applicable** as on.....With the department. **central excise / State commercial department** is due on M/s.....as on.....
10. That I will supply the Drug and Medicines per the designs given in Bid clause no 14 and as per the instructions given in this regard.
11. That I/We have carefully read all the conditions of e- Bid in Ref. no. F.02(368)/RMSCL/PROCUREMENT/DRUG/NIB-01/2023/50 Dated:- 06.01.2023 for Rate Contract cum Supply, of Drugs and Medicines (**Rate Contract for the period ending on 31.12.2023**) for Rajasthan Medical Services Corporation Ltd and accept all conditions of Bid, including amendments

-
if any. If case of typographical error found in submitted documents / affidavits, in this case we accept all the Terms and conditions of bid documents.

12. I/We agree that the Bid Inviting Authority forfeiting the Bid security Deposit and or Performance Security and blacklisting /Debarring/Banning me/ us for a period of 5 years or as deemed fit if, any information furnished by us proved to be false/fabricated at the time of inspection and not complying the conditions as per Schedule M of the said Act or at any time during the Bid process.

13. I/ we hereby declare under Section 7 of Rajasthan Transparency in Public Procurement Act, 2012. that:

- a. I/we possess the necessary professional, technical, financial and managerial resources and competence required by the Bidding Document issued by the Procuring Entity;
- b. I/we have fulfilled my/our obligation to pay such of the taxes payable to the Union and the **State Government or any local authority** as specified in the Bidding Document;
- c. I/we are not insolvent, in receivership, bankrupt or being wound up. not have my/our affairs administered by a court or a judicial officer, not have my/our business activities suspended and not the subject of legal proceedings for any of the foregoing reasons;
- d. I/we do not have, and our directors and officers not have, been convicted of any criminal offence related to my/our professional conduct or the making of false statements or misrepresentations as to my/our qualifications to enter into a procurement contract within a period of three years preceding the commencement of this procurement process, or not have been otherwise disqualified pursuant to debarment proceedings;
- e. I/we do not have a conflict of interest as specified in the Act, Rules and the Bidding Document, which materially affects fair competition.

14. The quoted rates of any items is not more than the price fixed by the govt. under the current drugs (Price control) order.

15. Our complete address for communication.....

.....
.....

.....Pin.....

Pan No.-----

E-mail address : -

Phone No. /Mobile No.....

16. Bank detail for e banking :-

Name of account holder

Full name of Bank with Branch

Address of BankPin.....

A/c no. with full digits.....

IFSC code

17. Authorized/nominating person

Name:

Designation:-.....

Aadhar Number:-.....

E-mail address:-.....

Phone No./Mobile No.....

Photograph of
Authorized/
nominating person

Signature of
Authorized /
nominating person

(Name of Deponent & Signature)
Designation

Verification

I.....S/o.....(Designation).....

Affirm on oath that the contents/information from para 1 to 17 as mentioned above, are true & correct to the best of my knowledge and nothing is hidden. I also declare on oath, that if any information furnished by me as above is found wrong, false, forged or fabricated; the Corporation will be at liberty to cancel the Bid for which I shall be solely responsible and the firm may be Debarred/Banned/ blacklisted / prosecuted for the same.

(Name of Deponent & Signature)

Witness :- (Name, Address & Signature)

1

2

*The GMP/WHO-GMP certificate must not be older than one year from the last date of Bid submission in case validity is not mentioned in the certificate.

-
Annexure – VIII
Ref. Clause No. 9 (2, 3)

List of Drugs with Specifications

S. No.	Code No.	Name of Drug with specification	Packing unit	Minimum labelled Shelf Life (In Months)	Estimated Bid Qty.	Remark
1.	90	Ceftazidime Injection IP 250 mg	Vial	24	188264	
2.	91	Ceftazidime Injection IP 500 mg	Vial	24	237784	
3.	169	Desferrioxamine Injection IP 500 mg / Vial (For I.M. Inj and I.V., S.C. Infusion) [169]	Vial	18	27542	
4.	183	Amiodarone Hydrochloride Injection IP 50 mg/ml	3 ml Amp(10 ampoules)	24	67746	
5.	233	Diatrizoate Meglumine and Diat Sod Inj USP 76%w/v (iodine = 370 mg/ml) [233]	20 ml Ampoule	36	17875	
6.	332	Tobramycin Ophthalmic Ointment USP 0.3% [332]	5 gm Tube in Mono Carton	24	663691	
7.	423	Hyaluronidase Injection IP Each vial contains Hyaluronidase IP 1500 I.U.	Vial	24	39890	
8.	475	Cefpodoxime Dispersible Tablets 50 mg	10x10 Tab Strip	24	4602480	
9.	525	Alpha Interferon Injection Interferon Alpha 2 concentrated Solution IP 3 Million Unit[525]	Vial	24	297	
10.	557	Urokinase Injection 5 Lac Unit (Lyophilized) [557]	Vial	24	16586	
11.	790	Multi vitamin Syrup Each 5ml contains :- Biotin 10-25 mcg Elemental Maganese 1.5-2 mg Elemental Selenium 30-50 mcg Elemental zinc 200-500 mcg Iodine 90-100 mcg Molybdenum 20-25 mcg Vitamin A 500-1000 mcg Vitamin B1 0.5-1 mg Vitamin B2 0.5-1 mg Vitamin B3 5-15 mg Vitamin B5 2-5 mg Vitamin B6 0.5-1 mg Vitamin C 40-60 mg Vitamin E 5-10 mg Vitamin D3 10-20 mcg Vitamin B12 1-1.5 mcg Mango/Pineapple/Strawberry Flavour	100 ml	18	5162550	
12.	NE17	MMA Drugs (in a combination pack) blister strip containing 1 tab Mifeprestone 200mg and 4 tab of Misoprostol 200mcg) [NE17]	1 Combipack (Kit) of 1 Tablet of Mifeprestone 200 mg & 4 tablet of Misoprostol 200 mcg in Blister Pack	24	17000	

S. No.	Code No.	Name of Drug with specification	Packing unit	Minimum labelled Shelf Life (In Months)	Estimated Bid Qty.	Remark
13.	NE60	Chlorthalidone 12.5mg Tablet [NE60]	10X10 Tablets	24	1022000	
14.	NE75	Morphine Sulphate 30 mg SR	10x10	24	1250	
15.	NE76	Hepatitis B Vaccine for HRGs	As per Annexure A	As per Annexure A	48666	Specification on Annexure A

(Specification for Hepatitis B Vaccine for HRGs)

Hepatitis B Virus Vaccine Specifications
(For NCB/LCB)

A. Specific requirements

Item:

Hepatitis B virus vaccine, shall meet the requirements as per Indian Pharmacopoeia (I.P.) and Rule-122B of Drugs and Cosmetics Act

The vaccine shall be currently registered in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The vaccine also shall be currently registered in the country of use (India) and shall meet all the requirements of the licensing authority of the country of use.

Description:

Hepatitis B virus vaccine may exist in two forms, i.e. as an inactivated (plasma-derived) vaccine and as a recombinant (DNA) vaccine. Hepatitis B virus vaccine (Inactivated) is a non-infectious inactivated liquid preparation derived from surface antigen of hepatitis virus (HBsAg). The production of vaccine is based on a virus seed lot system. Hepatitis B virus vaccine (Recombinant) is a non-infectious preparation containing the purified major surface antigen of hepatitis B virus (HBsAg). The antigen is manufactured by recombinant DNA technology by culturing genetically-engineered yeast cells lines which carry the gene that codes for the major surface antigen of the hepatitis B virus as approved by the competent authority. The purified antigen is finally adsorbed on aluminium hydroxide or aluminium phosphate. The vaccine must be free from all demonstrable viable microbial agents and found suitable for human immunization. It may contain a suitable stabilizing agent with anti microbial properties. Hepatitis B vaccine contains not less than 20mcg of hepatitis B surface antigen per ml.

Protocol and testing:

Complete Test Protocol along with samples of all batches should be sent to the Head of the vaccine testing laboratory i.e. Central Drugs Laboratory, Kasauli-173204;

For local manufacturers:

Complete Test Protocol and samples are taken and sent to by the Inspecting Officer duly sealed and signed by him or his authorized representative.

The vaccine should be dispatched to the consignee only on clearance from the Central Drugs Laboratory, Kasauli. The vaccine will be released on the basis of protocol scrutiny and testing of the vaccine by Central Drugs Laboratory, Kasauli.

Each batch should be accompanied with a certificate from the manufacturer that the vaccine meets the I.P. requirements.

Dosage size:

By intramuscular injection (Anterolateral part of thigh); when given as part of a primary immunization starting at 6 weeks of age. Three injections are given at monthly intervals. In all institutional deliveries a dose at the time of birth as early as possible and preferably within 24 hours.

Dose package:

Single-dose; multi-dose vials contain 10 paediatric doses 0.5ml, or 10 adult doses 1 ml.

Filling volume:

Final product should contain 15% overfill.

Storage temperature:

In light-resistant containers between +2 and +8°C; must not be frozen.

Shelf-life:

At least 24 months from date of manufacture when stored between +2 to +8°C ; at least 20 months must remain after shipment. The supplier will provide manufacturer's stability test data substantiating this 24 month shelf life in the proposed vial. At the time of inspection or acceptance for delivery to the country of destination, no more than 6 months shall have expired since the Date of manufacture (or date of beginning of the last satisfactory test for potency) shown on the Certificate of Analysis.

Labelling:

The label on each vial shall conform to the requirements of I.P. and shall appear in the language of English.

All labelling shall be indelible ink and shall withstand immersion in water and remain intact.

All labels shall state the name of the vaccine, name of the manufacturer, address of manufacturer, lot number, composition, concentration, dose and mode for administration, expiry date, storage temperature and any other marking that is appropriate.

VVM:

The label on each vial should include a Vaccine Vial Monitor (VVM) designed to meet the heat stability curve of the vaccine supplied. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The position of the VVM may be on the label or on the neck or on the cap as validated by the supplier

The Vaccine Vial Monitor (VVM) shall be as per WHO Specifications (please refer to Annex I).

Labelling for secondary packaging:

A label must be affixed either to the top and/or front surface of the secondary packages. It should indicate the type of vaccine, the name of the manufacturer, presentation, batch number, date of manufacture, date of expiry, quantity and storage conditions.

Labelling for tertiary packaging (insulated packaging):

The external surface of insulated packages should be either white or in the natural colour of corrugated carton. Dark colours must be avoided. All labels on tertiary packaging must be attached to all four sides.

Vaccine Rush: A label must be affixed to all four sides of the vaccine package in English/Hindi.

"Do not freeze" sticker in English/Hindi should be attached to all four sides of the vaccine package.

Numbering of tertiary packaging:

All boxes should be numbered consecutively. Shipping documents should be included in the box labelled number 1, and this box should be clearly labelled with the words

"Containing vaccine shipping documents".

Additional Labelling:

All the containers and other outer containers shall be marked with the statement "CGS NOT FOR SALE" in English.

All labels on containers i.e. vials/ampoules, cartons, tubes etc. as well as outer dropper should be marked with the statement "CGS NOT FOR SALE" in bold red letters in English.

Containers:

IP type 1 amber coloured glass tamper proof ampoule/vial or plastic container for parenteral preparation.

Closures:

Vaccine vials shall be fitted with closures that conform to IP requirements for injectable preparations.

Printed materials:

Two (2) information sheets, printed in English and Hindi, shall be included in each secondary package and shall include information as per Annexure III

B. Quality assurance

Compliance:

The Supplier shall guarantee that the products as packed for shipment

(a) comply with all provisions of the specification and related documents;

(b) meet I.P./Internationally (WHO as cited above) recognized standard for safety, efficacy and quality; (c) are fit for the

purposes made known to the Seller (d) are free from defects in

workmanship and in materials and (e) the product has been

manufactured cGMP included in Schedule M.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.
The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.
The Supplier shall provide a copy of **Validation record** with regards to process validation demonstrating batch to batch consistency and to confirm that the packaging complies with WHO requirements.
The supplier shall provide document that the batch conforms to the WHO requirements of **Shake test**.
The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.
The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.
The Supplier shall retain a sample of twenty (20) vials from each lot shipped for two years beyond the printed expiration date.
Chemical, physical and biological test data for in-process and finished product testing must be on record for each lot shipped and must be available to Purchaser's representatives when requested.

Inspection:

The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier's factory and/or warehouse at a mutually agreeable time prior to the shipment of the product.

Testing:

The Purchaser may cause independent laboratory testing to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on biological products.

C. Packing

Prior to and at the time of packing, the vaccines must be kept within the storage temperature limits recommended by the manufacturer.

Storage:

Supplier shall state storage volume occupied per infant dose of vaccine (storage volume includes the vaccine vial, packet containing the vaccine vial and any intermediate packaging).

Inner boxes:

_____ (number) individual glass vials or ampoules shall be contained in sturdy white cardboard boxes (of not less than 300 GSM) outfitted with individual segments for protecting and separating each vial.

Temperature monitoring devices:

To be included in all vaccine shipments to document whether temperature limits have been exceeded.

One electronic temperature device is included in each and every vaccine shipping carton

(Please refer to Annex II).

Prior to and at the time of packing, the vaccine must be kept at the storage temperature recommended by the manufacturer.

Vaccine manufacturer is required to validate their packaging twice for a period of 48 hours i) that the warmest temperature inside the insulated packing does not rise above +30°C in the continuous outside ambient temperature of + 43°C and ii) that the coolest storage temperature does not fall below +2°C in the continuous outside temperature of -5°C.

Over packing:

Box shall be over packed so that the vaccine remains refrigerated at between + 2 and +8°C and does not freeze. The containers must be suitable for export shipping in accordance with *WHO guidelines on the international packaging and shipping of vaccines* (WHO/V&B/01.05). The containers must have adequate insulation and or sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above +30°C in continuous outside ambient temperature of + 43 degrees C nor fall below +2°C in continuous external temperature of -5°C during transit and for a period of at least 48 hours after arrival at the airport of destination¹³.

Additional cushioning shall be provided, sufficient to protect the vials from breakage during transit and handling.

Exterior shipping cartons:

Product and printed materials, packaged as specified above, shall be packed in weather-resistant, triple-wall corrugated fibreboard cartons with a bursting test strength of not less than 1900 kPa. The overall dimensions of the exterior shipping cartons should be such that the product does not become damaged during transportation and storage.

Each international shipping carton should weigh less than 50 kg. It is important that individual boxes are not too heavy during transport as they are frequently loaded and offloaded manually at airports and intermediate stores.

¹³ When considering "best practices" for transport and storage of vaccines, reference should be made to current recommendations in the appropriate literature.

D. Markings

All containers and invoices must bear the name of vaccine, expiry dates of the vaccine and appropriate storage temperature.

Inner boxes:

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:

- Generic name and trade name of the vaccine
- Manufacturer's name and registered address
- Manufacturer's national registration number
- Lot or batch number
- Composition and concentration
- Number of vials contained in box
- Date of manufacture (month and year)
- Expiration date (month and year)
- Instructions for storage and handling^{14*}
- Place of manufacture (Made in _____)

Exterior shipping cartons:

The following information shall be stencilled or labelled on the exterior shipping cartons on two opposing sides in bold letters at least 'Ariel font size 14' high with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name and trade name of the vaccine
- Lot or batch number
- Date of manufacture (month and year)
- Expiration date (month and year)
- Manufacturer's name and registered address
- Manufacturer's national registration number
- Destination country license or registration number
- Consignee's address and emergency phone number including mobile number
- Destination airport
- Contract number
- Number of vials contained in the carton
- Gross weight of each carton (in kg)
- Carton containing ----- secondary packages
- Instructions for storage and handling^{15*}
- Place of manufacture (Made in _____)

¹⁴ * Markings on inner boxes should state clearly that the reconstituted vaccine is good for 6 hours only; additional text to be provided by Purchaser.

¹⁵ * To be provided by Purchaser.

E. Documentation

Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the vaccine being supplied.

Advance notice of arrival and advance shipping documentation:

Copies of the documentation for the goods to be shipped must be sent at least seven days in advance of arrival of the shipment. In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply. The consignee(s) should be intimated well in advance by registered letter/telegram telephone, so that vaccines are collected from airport immediately after arrival. Copy of the communication from the supplying firm should be endorsed to the Assistant Commissioner (I) and Deputy Director (UIP), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi for information.

The documentation must include the following:

- Pre-advice defined by the Purchaser
- Airway bill (AWB);
- Supplier's invoice;
- Packing list;
- Lot release certificate (LRC) issued by the national regulatory authority (NRA) of the country of manufacture for each lot of vaccine supplied; and
- Any other document, certificate or instruction specified in the individual order.

The documents should be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignee, the Purchaser, and any other parties specified in the individual contract.

The pre-advice must contain the following information:

- Purchase order reference;
- Consignee requisition reference;
- Number of packages, gross weight (in kilograms) and volume (in cubic meters);
- Type of vaccine, total number of vials and number of doses per vial/ampoule/tube;
- Value of shipment (in Indian Rupees and/or in US \$);
- AWB and flight number(s);
- Date and time for place of departure, transit (if applicable), and arrival;
- Instructions for collection;
- Any other information specified in the individual contract must also be included for the consignee.

The following information shall be stated on the airway bill:

- Consignee's name, address, telephone number (including mobile no) and e-mail ID.
- Purchase order reference;
- Consignee's requisition reference;
- Type of vaccine and quantity;
- Instructions to: "Telephone consignee upon arrival (*repeat telephone number*)";
- Handling information: "Medicines – Vaccine – For human use – Highly perishable – Not to be delayed."

The following instruction should be stated in the AWB: "Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at +2°C to +8°C."

F. Dispatch

Vaccines should travel by a direct route wherever possible, road transport may be used if accompanied by attendant. Where trans-shipment is unavoidable, the journey should be planned through airports that:

- a) have cold storage facilities, and
- b) are located in countries with a temperate climate.

The maximum transit time from the manufacturer to arrival at the airport of final destination must not exceed 48 hours.

Shipments should be scheduled to arrive outside weekends and/or public holidays in the recipient country and airline bookings should be made well ahead of the date of departure.

- Vaccines must not be transported with radioactive products, fish or meat;
- Correct cold-chain procedures must be observed during transit, warehousing and shipping (i.e., all vaccines must be kept in temperature-controlled environments at all times throughout the shipment process);
- Reactivation of the refrigeration process of shipments must be performed in accordance with the instructions of the supplier of each shipment whenever deemed necessary;

G. References

- 1) Indian Pharmacopoeia 2007, Indian Pharmacopoeia Commission, Government of India; Ministry of Health & Family Welfare. Ghaziabad.
- 2) British Pharmacopoeia 2007, Volume III, page 24
- 3) Guidelines on the international packaging and shipping of vaccines. WHO 2005; Department of Immunization, Vaccines and Biologicals. WHO/IVB/05.23.
- 4) Procurement of vaccines for public-sector programmes- A reference manual. WHO/IVB/03.16; 2004.

Annexure-I
SPECIFICATION FOR VACCINE VIAL MONITORS (VVM)

Specification reference : E6/ IN5
Applies to test procedures : E6/ Proc/5

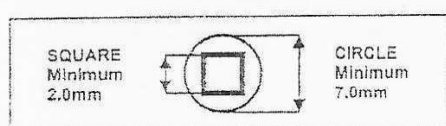
Purpose

Vaccine vial monitors serve primarily to warn health workers when the cumulative heat exposure of a vial of vaccine has exceeded a pre-set limit, beyond which the vaccine should not be used. In addition, changes in the appearance of the VVM before this limit is reached will serve to guide health workers to first use more exposed vials of vaccine.

Format and dimensions:

The VVM is a circle of colour, minimum 7.0mm with a square of colour, Minimum dimension 2.0 x 2.0mm positioned in the centre of the circle (See Figure 1).

The ratio of the area of the square to the area of the circle (including the square) is at least 0.1, whatever dimensions are chosen.



Design:

The circle of the VVM acts as a static, reference colour and the square is a changing, active colour change device. The colour is limited to a change of shade, from light to dark. Any colour is permitted for the VVM design, but changes in hue are not permitted.

Colour:

The colour density change of the indicator is illustrated in the Figure 2 below. At the start point the colour of the square is lighter than the circle. The end point is indicated when the colour of the square matches the circle. The end point is exceeded when the colour of the square is darker than the circle. The following paragraphs describe the colour change in more detail.

Start point		Square lighter than circle
End point		Square matches the circle
End point exceeded		Square darker than the circle

Figure 2. The colour density change of the Indicator (The central square is the active surface)

1 Replaces the previous version of 13 August 1999

Definition of the start-point

The colour of the active surface of the VVM at the time of the vaccine vial is

called the 'start point'.

At the start point, the colour density of the square as measured by a colour Densitometer² must be lighter than the circle by a difference of at least 0.25 OD Densitometer units.

Definition of the end-point

The colour of the active surface of the VVM at the limit of use of the vaccine vial is called the 'end-point'.

The end point is reached when the difference in the average colour density obtained from readings at least two different points on the circle and the colour density of the square is 0.00 OD, as measured by the densitometer. The end point is exceeded when the colour of the square is darker than the colour of the circle.

Homogeneity of the reference colour

The colour density of one 2mm diameter portion of the circle must be within 0.01 OD of the colour density at any other two 2mm diameter portions of the circle, when measured with a colour densitometer.

VVM reaction rates:

Reaction rates are specific to four different models of VVM, relating to four Of vaccines according to their heat stability at two specific temperature points

(See table 1)

Table 1: VVM reaction rates by category of heat stability

Category: (Vaccines)	No. of days to end point at +37°C	No. of days to end point at +25°C	Time to end point at +5°C
VVM30 HIGH STABILITY	30	193	> 4 years
VVM14 MEDIUM STABILITY	14	90	> 3 years
VVM7 MODERATE STABILITY	7	45	> 2 years
VVM2 LEAST STABLE	2	NA*	225 days

*VVM (Arrhenius) reaction rates determined at two temperature points

At +37°C, RH 33% +/-5% and RH 75% +/-5%, at least 90% of VVMs tested Should reach the end point within a range of time whose upper limit is shown in Table 1 or a period set by the vaccine manufacturer, based on published vaccine stability data, and whose lower limit is 25% below the upper limit (See Figure 3).

At +25°C (ambient humidity in submerged plastic/foil pouch) at least 90% of VVMs tested should reach the end point within a range of time whose upper limit is shown in Table 1 for VVM30, VVM14 and VVM7 categories, or a period set by the vaccine manufacturer, based on published vaccine stability data, and whose lower limit is 40% below the upper limit (See Figure 3).

At 5°C (ambient humidity in submerged plastic/foil pouch), all VVM30, VVM14 and VVM7 samples should reach the end point after the lower time limit specified in Table 1. Conformance can be determined by extrapolation from high temperature (25°C and 37°C) data. At 5°C (ambient humidity in submerged plastic/foil pouch), at least 90% of VVM2 samples tested should reach the end point within a range of time whose upper limit is 225 days and whose lower limit is 40% below the upper limit (see Figure 3).

A tolerance is allowed in the above tests for up to 5% of VVM samples tested to reach the end point after the upper limit and 5% before the lower limit (See Figure 3).

The colour change shall be monotonic in its response to cumulative heat exposure within the limits of the allowed variation. The observer shall be able to distinguish between unchanged, 50% and the end point of the indicator.

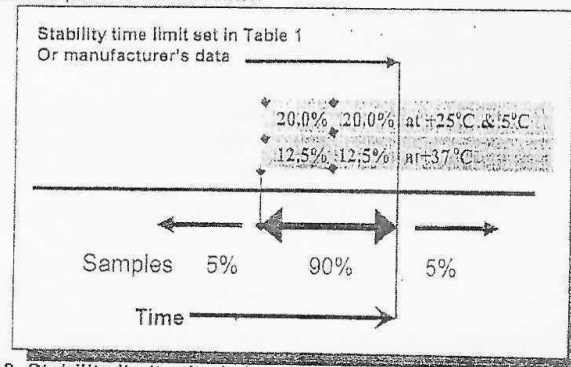


Figure 3. Stability limit criteria by sample group

Global Measurement Accuracy:

The allowable total error for measuring the difference the colour of the circle and Square is $\pm 0.04\text{OD}$ when using an X-rite 404 GS(X) colour reflectance Densitometer. Major sources of error are instrument error for both the circle and square, repeatability, and variation in end point caused by an allowed temperature variation of $\pm 0.2^\circ\text{C}$.

Water Bath Precision and Control:

The VVMs should be tested in water baths controlled to within $\pm 0.2^\circ\text{C}$. (Any additional 0.1°C variation in temperature control requires an allowance for additional measurement error.)

Reversion

The indicator shall not revert to a lighter colour at any point in its life when exposed to conditions likely to be found during normal use. After the endpoint is reached, the square shall remain the same colour as the circle or become darker than the circle.

Integrity of VVMs

The integrity of VVMs depends on the presentation of the vaccine:

For liquid vaccines:

The VVM shall be permanently attached to the vaccine vial, even after the vial has been opened and remain readily observable before, after and during use. Prior to opening, the VVM should not be removable; it should resist removal from the vaccine vial as much as a label meeting current requirements.

For freeze dried vaccines:

The VVM shall be attached to the vaccine vial or ampoule, remaining readily observable until the vial or ampoule is opened but not observable after opening. Prior to opening, the VVM should be removable: it should resist removal from the vaccine vial as much as a label meeting current requirements.

Safety

The performance of the VVM shall not be able to endanger human health. The materials of the VVM shall be non-toxic and non-irritant. The VVM should meet any requirements in force concerning toxicity of labels or packaging in the country of manufacture.

Annex II: Temperature Monitoring Devices

Table 1: Specifications of the electronic devices for all national and International shipments

Storage temperature Range:	-20°C to +70°C
Operating temperature Range:	-20°C to +55°C
Display visibility Range:	-10°C to +55°C
Temperature measuring accuracy	± 0.5°C or better
Time measuring accuracy	± 10 seconds per day, or better
Initial delay (see point 2 below)	1 hour
Recording period	10 days
Storage before START	minimum of 18 months
Data retention after STOP	minimum of 6 months

A For specific devices with these features, refer to the WHO web site:
<http://www.who.int/vaccines-access/vacman/pis/pqs.htm>

The electronic devices should, at a minimum, meet the specifications outlined in Table 1 (above) and have the functions outlined below.

- 1) A "start" function to activate the device at the time the carton is being loaded with vaccine.
- 2) A "stop" function to allow the recipient to stop the recording when the vaccine arrives at its destination.
- 3) A one hour "Initial delay" function so the device can acclimatize to the temperature inside the shipping carton before it starts recording.
- 4) A "history" function to provide details of violations of the temperature limit in terms of time, range and duration. This function is primarily to provide information for the use of the procurement agency.
- 5) A liquid crystal display (LCD) screen to provide a visual display of the information and also to show the symbol that indicates whether the device is functional or not. This symbol, and also the alarm indicator, should be static (i.e. should not flash or blink) so as to be visible when the screen is scanned or photocopied for documentation purposes.
- 6) An alarm set according to WHO's recommended settings (see Tables 2 and 3 below).

Table 2: WHO-recommended alarm settings for national/international shipments of DTP, DT, TT, HepB and combination vaccines

Temperature	Alarm type	Period for triggering the alarm
45°C	single event	1 hour
30°C	cumulative	10 hours
-0.5°C	single event	1 hour

Table 3: WHO-recommended alarm settings for all national and international shipments of OPV and freeze-dried BCG, measles, MMR vaccines

Temperature	Alarm type	Period for triggering the alarm
45°C	single event	1 hour
30°C	cumulative	10 hours
10°C	cumulative	20 hours

Vaccine manufacturers are required to validate their packaging twice for a period of 48 hours:

- i) at ambient temperatures under +43°C and
- ii) at ambient temperatures under -5°C.

This validation is critical to ensure that the packaging complies with the above requirements and will not set off an alarm.

Batteries for electronic devices do not perform under extremely cold temperatures, such as when vaccines are being transported with dry ice.

Each electronic device should be attached to a backing card that includes the information outlined below, in the appropriate language.

1. The type of device:

Type 1: for DTP, DT, TT, HepB and combination vaccines

Type 2: for OPV and freeze-dried BCG; measles, MMR vaccines

2. For the person packing/sending the shipment:

- a) Instructions on how to activate the device;
- b) A reminder that one device must be placed in each shipping carton;
- c) Space for the following information to be entered:
 - the supplier's name;
 - date and time of the packing;
 - vaccine purchase order number;
 - vaccine type.

3. For the person receiving the shipment:

- a) Instructions on how to stop the device;
- b) Illustrations to show information on the LCD screen – how it will indicate problems/no problems and the alarm-status display;
- c) Tables 4 and 5 (below) showing what to do.

Table 4: Information to be displayed on the backing card of electronic device – Type 1 (for DTP, DT, TT, HepB and combination vaccines)

Alarm temperature	What to do with vaccines
45°C	Contact Consignee
30°C	Contact Consignee
-0.5°C	Conducts shake tests. USE vaccine if passes. Inform Consignee of test results.

Shake test guidelines can be found on Guidelines on the international packaging and shipping of vaccines. WHO 2005; Department of Immunization, Vaccines and Biologicals. WHO/IVB/05.23.

Table 5: Information to be displayed on the backing card of electronic device – Type 2 (for OPV and freeze-dried BCG, measles, MR, MMR, lyophilized Hib, yellow fever and meningitis vaccines)

Alarm temperature	What to do with OPV	What to do with other vaccines
45°C	Contact Consignee	Contact Consignee
30°C	Contact Consignee	Contact Consignee
10°C	Contact Consignee	Accept

SPECIFICATIONS:

Alarm setting	Type 1: for vaccine: DTP,DT, TT, Hep B and combination vaccines		Type 2: for vaccine: OPV, freeze dried BCG, measles and MMR	
	>=+45°C	1 hour single	>=+45°C	1 hour single
	>=+30°C	10 hours cumulative	>=+30°C	10 hours cumulative
	>=-0.5°C	1 hour single	>=+10°C	20 hours cumulative
Initial start delay	1 hour		1 hour	

MODEL INSERT

Hepatitis-B Vaccine

DESCRIPTION:

Hepatitis B virus vaccine may exist in two forms, i.e. as an inactivated (plasma-derived) vaccine and as a recombinant (DNA) vaccine. Hepatitis B vaccine contains not less than 20mcg of hepatitis B surface antigen per ml.

ADMINISTRATION:

The vaccine should be injected intramuscularly. The preferred site of injection is outer mid-thigh (infants)/outer upper arm (children and adults). (An injection into a child's buttocks may cause injury to the sciatic nerve and is not recommended.)

It must not be injected into the skin as this may give rise to a local reaction. 1 dose is 0.5 ml. A sterile needle and sterile syringe should be used for each injection. Once opened multi-dose vials should be kept between +2°C and +8°C. Opened vials of vaccine may be used in subsequent immunization sessions until, a new shipment of vaccine arrives providing that the conditions described in WHO/EPI/LH15/95.1 are met.

IMMUNIZATION SCHEDULE:

By intramuscular injection (Anterolateral part of thigh); when given as part of a primary immunization starting at 6 weeks of age. Three injections are given at monthly intervals. In all institutional deliveries a dose at the time of birth as early as possible and preferably within 24 hours.

SIDE EFFECTS:

Local soreness and redness, rarely anaphylactic reaction

CONTRAINDICATIONS:

Anaphylactic reaction to a previous dose

STORAGE:

HepB vaccine should be stored and transported between +2°C and +8°C. IT MUST NOT BE FROZEN.

PRESENTATION:

The vaccine comes in vial of 10 doses.

Note:-

The above quantity mentioned for this supply cum rate contract is indicative and may vary as per the actual requirement of hospitals.

The bidder should quote rate for the above mentioned packing unit only.

General Requirement:-

1. The manufacturer should ensure Stability of the formulations and its ingredients in the packing supplied.
2. The blister packing of tablets/Capsules should have Aluminium foil back.
3. Strip packing should be of Aluminium / Alu- Alu foils.
4. Aluminium foil strips refer to thickness not less than 40 microns.
5. The rigid PVC used in blister packing should be of not less than 250 microns.
6. Small tablets packed in blister should be packed to facilitate easy removal of a tablet without breaking/ crushing.
7. Containers for 400 ml (or 400 gm) or more, should have an inner lid also.
8. Syrup and Suspension should be palatable enough.
9. The measuring cap / dropper supplied with oral liquid formulation should have suitable marking.
10. The minimum size (length x breadth) of a blister strip shall be 6.5cm X 3cm.
11. Generic name of a drug should be printed in clearly legible bold letters. The font size of the name of drug on any tablet strip/ blister shall not be less than '9' in bold capital letters of Times New Roman or Arial font, e.g., LOSARTAN TABLETS IP even on small strips/ blisters. The font size shall be correspondingly bigger on bigger strips / blisters. Besides this, other contents on the label should also be legible.
12. The stereo printing of batch no. , Mfg date, Exp date on the reverse side of strip/blister should run atleast two times.
13. **Quote rate in BOQ for the packing exactly given in annexure VIII. For example**
 - **If the packing unit is given for 10x10 tablets / capsule, the rate should be quoted for 10x10 tablets / capsule, and not for 1 tablet / capsule or 10 tablets/ capsule.**
 - **If the packing unit is given for 10x10x1 tablets / capsule, the rate should be quoted for 10x10 tablets / capsule, and not for 1 tablet / capsule or 10 tablets/ capsule.**
 - **If the packing unit is given for 10x14 tablets / capsule, the rate should be quoted for 10x14 tablets / capsule, and not for 1 tablet / capsule or 10 tablets/ capsule.**
 - **If the packing unit is given for 2 ml ampoule (25 ampoules), the rate should be for 25 ampoules and not for 1 ampoule or 10 ampoules etc.**
If the packing unit is given for 2 ml ampoule (10 ampoules), the rate should be for 10 ampoules and not for 1 ampoule etc.

RAJASTHAN MEDICAL SERVICES CORPORATION LTD
GUIDELINES FOR BLACK LISTING / DEBARRING OF PRODUCT
OR COMPANY

1. ON SUBMISSION OF FALSE, FORGED OR FABRICATED DOCUMENTS OR CONCEALING OF FACTS:

1.1 The tenderer who submits false, forged or fabricated documents or conceals facts with intent to win over the tender or procure purchase order; EMD of such tenderer firm will be forfeited and firm will be liable for debarring for a period of not Less than 2 years. The firm will also be liable for Legal action depending on the facts & circumstances of the case.

2. ON ACCOUNT OF FAILURE TO ENTER INTO AGREEMENT OR WITHDRAWAL AFTER AGREEMENT OR REFUSAL / FAILURE TO SUPPLY:

2.1 The successful Bidder fails to execute the agreement after being declared as L-1, L-2 or L-3 etc. to perform the obligations under the Bid conditions, Bid Security Deposit of such Bidder firm shall be forfeited.

If an LoA for more than one products is issued to a successful bidder and he/she/it fails to execute agreement for few items, in such case, a penalty of Rs. 2.00 lac and in case of MSME of the State of Rajasthan Rs. 50,000 shall be imposed on successful bidder and the product for which agreement is not executed shall be debarred for a period of not less than 3 years.

2.2 The successful tenderer after entering into an agreement withdraw or fail to honour commitments as per tender conditions, Security Deposit of such tenderer firm will be forfeited and firm will be liable for debarring for a period of not Less than 2 years.

3. ON ACCOUNT OF NON-SUPPLY:

3.1 The supplier shall start to supply according to tender condition from the date of purchase order and shall complete the supplies within 60/75 days as mentioned in Purchase Order or as stated in tender condition.

3.2 RMSC will be at liberty to accept or reject the supply made belatedly as per the terms and conditions of the tender documents. In the event of

-

acceptance of delayed supply the liquidated damages shall be imposed at the rate stipulated in conditions of the tender document.

3.3 If the supplier fails to execute the purchase order and informs RMSC about its inability to execute the order and non-compliance of the purchase order due to act of vis-majeure, then the Managing Director, RMSC will issue appropriate order on merits of case.

3.4 If the supplier fails to execute atleast 50% of the quantity mentioned in single purchase order and such failure in supply continues for three purchase orders, then supplier firm will be liable for debarring for a period of 2 years. As a result such supplier will be ineligible to participate in any of the tenders for particular item(s) of drugs / medicines for a period of 2 years.

4. ON ACCOUNT OF QUALITY FAILURE OF DRUGS & MEDICINES:

4.1 The drugs supplied by the suppliers to the District Drug Warehouses are quarantined and samples of each and every batch of drugs /medicines are drawn on random basis and forwarded to Quality Control Wing of RMSC at the headquarter. The samples are then sorted; common batches pooled, coded and are sent to the empanelled laboratories for quality control test as per the QC Policy of RMSC.

4.2 Samples of all sterile surgicals & sutures items falling in the categories of drugs will also be drawn as per above policy and all of them will be subjected essentially for sterility testing.

4.3 If such samples **pass** quality test in all respects, RMSC will instruct its Warehouses to issue items of drugs to various hospitals / institutions

4.4 If the sample fails in quality test and report is received certifying that sample is **not of standard quality**, the drugs of the batch will not qualified for issue and supplier shall be informed to take back stocks of such batch, which failed the quality test and other consequences would follow as per the conditions in the tender documents.

Minor defects

4.5 (1) If one batch of a particular item supplied during contract period fails in any of the quality test conducted by the tender inviting authority and/or by

-

the Drugs Control Department, then Penalty of not less than 5.0% of Purchase Order value of that particular item shall be levied."

4.5 (2) If two batches of a particular item supplied during contract period fail in any of the quality tests conducted by the tender inviting authority and/or by the Drugs Control Department, then that particular product of that firm will be blacklisted for a period up to 3 years but not less than 06 months in any case.

(*Tablets/Capsules failing in dissolution test and active contents found 70% and above for thermo labile products and upto 5% less than the prescribed limits for thermo stable products.)

Grossly substandard

4.6 (1) If **any batch of a particular item** supplied under a tender tenure by the supplier is declared as **Not of Standard Quality** by an empanelled lab or Govt. Lab which falls in **grossly substandard** category and such failure is further confirmed by another empanelled lab / Govt. Lab, then the product shall be liable for debarring for a period of not Less than one (1) years.

(2) If **two or more batches** supplied under a tender tenure by the supplier is declared as **Not of Standard Quality** by an empanelled lab or Govt. Lab, which falls in **grossly substandard** and such failure is further confirmed by Govt. Lab, then the **Product** shall be liable for debarring for a period of not less than two (2) years.

4.7 If the supplier supplied **more than one drug** (subject to a minimum of 6 drugs) during a tender duration and 50% of such drugs are blacklisted, the **firm** is liable to be blacklisted for a period of **2 years** from the date of intimation after observing the procedure.

Spurious or Adulterated

4.8 In case, any sample (even one batch) is declared as **Not of Standard Quality** by an empanelled lab or Govt. Lab which falls in **Spurious or Adulterated** category and if such failure is further confirmed by Govt. Lab during its entire shelf life, the **Company** shall be liable for debarring for a period of **not less than 5 years**.

4.9 If any statutory sample of RMSC supply drug is drawn by Drugs Control Officer on suo-moto basis or on complaint and if it fails in quality

parameters, the report is conclusive till it is challenged by supplier / company. If it is challenged then the report of Director, C.D.L., Kolkata shall be conclusive and action as contemplated in foregoing paragraphs will be initiated in the matter of debarring of product or company. However if failure is of such nature wherein Drugs Controller of State grants prosecution sanction under Drugs & Cosmetics Act, 1940, then even failure of such one batch shall be considered adequate for debarring the product for not less than 2 years and in case of involvement of three different products the **Supplier / Company** as a whole shall be liable for debarring for a period of not Less than 3years.

5 PROCEDURE IN THE EVENT OF QUALITY FAILURE WILL INVOLVE THE FOLLOWING STEPS:

- 5.1 On receipt of adverse quality test report from empanelled lab or Govt. Lab of a quarantined stock, instructions will be issued immediately through e-mail to the concerned District Drug Warehouses to not to release such stock and entries be made by QC Cell at headquarter in e-aushadhi software for batch rejection i.e. not to be released for distribution to institutions / DDC's.
- 5.2 Warehouse In-charge will take appropriate measures immediately to segregate such stock and label all cartons as "NOSQ Drugs-Not for release" and shift it from quarantine area to Non-Release / Rejected Drugs Area (which is under lock & key) till its lifting by the supplier.
- 5.3 Immediately on receipt of NOSQ report, the second sample should be sent to another empanelled lab / Govt. Lab by the by QC Cell.
- 5.4 The supplier shall be informed immediately about the test results and instructions be issued to lift the entire stock at supplier's expenses of such batch no. drug which is declared as "NOSQ" by the empanelled lab / Govt. Lab. However, in case of serious quality failure i.e. if drug is declared or adjudged spurious, adulterated or grossly substandard, one of drug warehouse In-charge will be directed to contact the District Drugs Control officer for drawing statutory sample of such batch as per Act. The DDW In-charge has to keep adequate quantity of such drug for statutory sampling by Drugs Control officer.

-
- 5.5 In case of drug declared as **Not of Standard Quality** on subsequent sampling after the batch was released the procedure given in sub-Para 5.2 will be followed in respect of stock available with the warehouse. In respect of stock already issued and drug warehouse In-charge will take immediate steps to RETRIEVE the unused stock of such drugs from all such institutions and D.D.C.s by all possible mode and means and he/she will ensure that no such NOSQ drug is further distributed to the patients and ensure effective recall.
- 5.6 On receipt of test report from empanelled lab / Govt. Lab, show cause notice will be issued immediately to the concerned supplier calling for explanation within 3 days from the date of receipt of notice in respect of quality failure of concerned batches of drug. The supplier will be required to submit the batch manufacturing record, batch analysis report, raw material purchase record & raw material test reports etc. Opportunity for personal hearing, if desired by supplier, may also be accorded.
- 5.7 On confirmation of the test result by the second laboratory, the case will be referred to the disciplinary committee of RMSC for further action.
- 5.8 In case when the second report is contradictory to the first report, the statutory sample will be sent to Govt. Lab, whose report will be final and if the sample has been tested by the Govt. Lab at any stage, its report will be conclusive & final unless challenged as per provisions of Drugs & Cosmetics Act, 1940.

6. EXAMINATIONS OF ISSUES BY DISCIPLINARY COMMITTEE OF RMSC

- 6.1 Each & every case of submission of false documents, failure to execute agreement, non-supply or quality failure, etc. will be referred to disciplinary committee of RMSC for examination on a case to case basis for making appropriate technical recommendation to Managing Director for further appropriate action.
- 6.2 The recommendations of disciplinary committee will be placed before the Managing Director, RMSC who shall take appropriate action which may deem fit in the light of facts & circumstances of the case by way imposing

-
penalty or debarring or Debarring of the particular product or supplier/
company.

6.3 If, the quality failure is of such nature that a particular product has been blacklisted according to the procedure stated above, the supplier will not be eligible for participating in any of the tenders for the particular item floated by RMSC for the specified period. For such purpose period of debarring will be counted from date of issue of order and it will be deemed to be over on completion of the period and as such no fresh orders will normally be required for re-eligibility purpose. Similarly if the supplier /company is blacklisted the supplier will not be eligible for participating in any of the tenders for any of the items during blacklisted period.

7. POWER OF REVIEW:

Subsequent to the action taken on the basis of available facts if some new facts & evidences such as reversal of test results findings by Appellate Laboratories etc. are brought to the notice of the corporation, the Managing Director of RMSC will have the right to review the earlier action. He may seek advice from the disciplinary committee in such matters.

8. RIGHT TO APPEAL:

Any supplier / company against whom the above action is taken may prefer an appeal within 30 days of date of debarring order to the Principal Health Secretary, Medical & Health Department, Govt. of Rajasthan who shall decide the same.

9. SAVINGS :

The debarring of particular product or supplier / firm will be done without prejudice to other penalty which may be imposed as per the conditions of tender documents and also to other actions which may be initiated under Drugs and Cosmetics Act 1940 or any other law of land. RMSC will display names of such blacklisted products and companies on its website and also circulate the same among all stakeholders viz. PSME, DM&HS, DC including respective State Drug Controllers where the supplier / company is located.

10. JURISDICTION:

-

In the event of any dispute arising out of the orders and implementation thereof, such dispute shall be subject to the jurisdiction of the Courts of Jaipur City only or Hon'ble Rajasthan High Court, Bench at Jaipur.

11. EXPLANATIONS:

- (i) Increase in the cost of raw materials, power cut, Labour strike, insolvency, closure of the factory would not be considered as act of vis-majeure.
- (ii) The Spurious, Adulterated, Grossly sub-standard drug shall have the explanation as per guidelines issued by Govt. of India for taking action on "Not of Standard quality drugs."

On the basis of quantitative analysis (Assay), the NOSQ drug shall be distinguished in the following manner :-

Category of NOSQ drugs	Active ingredient content (Assay)	
	Thermo stable	Thermolabile
Minor	Upto 5% less than the prescribed lower limit	Above 70% to the prescribed lower limit
Grossly Substandard	Below 5% of the prescribed lower limit to 50%	70% to 40%
Spurious	Below 50%	Below 40%

- (iii) Purchase Orders, if any, already issued before taking any debarring action or replacement orders given in past will not be affected in view of action taken as per above guidelines but all strict quality checks shall be observed for each supply of products.
- (iv) The action proposed as above is not in conflict to any express conditions laid down in corresponding tender and in case of any overlapping, the tender condition will prevail.

FORM NO. 1 [See rule 83 of RTPP]

Memorandum of Appeal under the Rajasthan Transparency in Public Procurement Act, 2012

Appeal No..... of.....

Before the..... (First/Second Appellate Authority)

1. Particulars of appellant:

- (i) Name of the appellant:
- (ii) Official Address, if any:
- (iii) Residential address:

2. Name and address of the respondent (S):

- (i)
- (ii)
- (iii)

3. Number and date of the order appealed against and name and designation of the officer/ authority who passed the order (enclose copy), or a statement of a decision, action or omission of the Procuring Entity in contravention to the provisions of the Act by which the appellant is aggrieved:

4. If the Appellant proposes to be represented by a representative, the name and postal address of the representative:

5. Number of affidavits and documents enclosed with the appeal:

6. Ground of appeal:

.....
.....
..... (Supported by an affidavit)

7.

Prayer:

.....
.....

Place.....

Date.....

Appellant's Signature

UNDERTAKING FOR EMPANELMENT

I Name.....S/o.....Age.....Prop./Partner/Director/
Power of attorney holder of firm M/s.....situated at (Complete
address of Mfg. unit).....bearing drug license on Form 25 & 28 or
form 10 bearing Number..... &.....respectively,
issued on dated.....valid/Renewed up to.....do here
by declare on oath as follows:-

1. That I have applied for empanelment for supply of Drugs & Medicines for the items I have quoted in the bid as enlisted in Annexure –VII
2. That I/We have carefully read all the conditions of E- Bid in Ref. no. F.02(368)/RMSCL/PROCUREMENT/DRUG/NIB-01/2023/50 Dated:- 06.01.2023 for supply Cum rate contract and empanelment for supply of Drug and Medicines For Rajasthan Medical Services Corporation Ltd and accept all conditions of Bid, including amendments if any.
3. That I will be considered empanelled for the items which my bid have been declared technically responsive.
4. That I have deposited the required fees for empanelment .

Date

**Name & Signature
with Seal**

Supplier Consolidated Invoice

Name of Supplier: Complete Address: E-mail ID:											
DL NO.:						<u>GST No.:</u>		<u>HSN Code</u>		Invoice No.: Date:	
Purchaser: Managing Director Address: Rajasthan Medical Services Corporation Ltd, Gandhi-Block, Swasthaya Bhawan, Tilak Marg, C-Scheme, Jaipur Phone No. 0141- 2228066 <u>RMSCL GSTIN.08AAFCR2824M1Z3</u>								Purchase Order No.: Date:			
Name of Item/Description :						Drug Code (RMSCL) :					
S.No	Name of DDW	Ordered Qty.	Invoice/Challan no.	Date	Packing Size	Batch No.	Mfg. Date	Exp. Date	Quantity Supplied in No. (Batch wise)	<u>Basic Rate (without GST)</u>	<u>Basic Amount (without GST)</u>
1	2	3	4	5	6	7	8	9	10	11	12
Remarks:						Total Basic Amount					
						<u>Rate of (%) GST(CGST)</u>					
						<u>Rate of (%) GST(SGST)</u>					
						<u>Rate of (%) GST(IGST)</u>					
						<u>Total GST Amount(CGST+SGST+IGST)</u>					
						<u>Grand Total (Basic Amount+ GST Amount)</u>					

Authorised Signatory

Analytical Report Regarding Quality

Name of Supplier:-						
Address:-						
PO No:-			Date:-			
Drug Name:-						
Details of in house test report:-						
S. No.	Name of Lab.	Test report No.	Date	Batch No.	Qty. Supplied	Result
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						

**Authorised
Signatory**

Security form (Bank guarantee)

To,

Managing Director Rajasthan Medical Services Corporation Ltd

WHEREAS.....(Name of Supplier)

Hereinafter called “the Supplier” has undertaken, in pursuance of
Contract (Letter of Acceptance)

No.....dated.....2023 to

supply.....(Description of
Goods) hereinafter called “the Contract”.

AND WHEREAS it has been stipulated by you in the said Contract that
the Supplier shall furnish you a bank Guarantee from a Scheduled Bank
for the sum specified therein as security for compliance with the
Supplier’s performance obligations in accordance with the Contract.

AND WHEREAS we have agreed to give the supplier a Guarantee:

THEREFORE WE hereby affirm that we are Guarantors and responsible
to you, on behalf of the Supplier, up to a total of
.....(Amount of the Guarantee
in Words and Figures) and we undertake to pay you, upon your first
written demand declaring the Supplier to be in default under the said
Contract and/or any other contract or for set off any other dues pending
against the supplier, without cavil or argument, any sum or sums within
the limit of(Amount of Guarantee) as aforesaid, without
your needing to prove or to show grounds or reasons for your demand or
the sum specified therein.

This Bank guarantee is payable at Jaipur Branch

This guarantee is valid until the.....day
of.....2025.....

Signatures and Seal of Guarantors

Date.....

Address:.....

.....

**Note:- The validity of bank guarantee should be for 24 months from the date of
issuance of Bank Guarantee.**